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National Primary Drinking Water Regulations: Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH–FRL–6570–5]

RIN 2040–AD18

National Primary Drinking Water Regulations: Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this document, EPA is proposing the Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule (LT1FBR). The purposes of the LT1FBR are to: Improve control of microbial pathogens in drinking water, including *Cryptosporidium*, for public water systems (PWSs) serving fewer than 10,000 people; prevent increases in microbial risk while PWSs serving fewer than 10,000 people control for disinfection byproducts, and; require certain PWSs to institute changes to the return of recycle flows within the treatment process to reduce the effects of recycle on compromising microbial control. Today's proposal addresses two statutory requirements of the 1996 Safe Drinking Water Act (SDWA) Amendments. First, it addresses the statutory requirement to establish a Long Term Final Enhanced Surface Water Treatment Rule (LTESWTR) for PWSs that serve under 10,000 people. Second, it addresses the statutory requirement to promulgate a regulation which ''governs'' the recycle of filter backwash within the treatment process of public utilities.

Today's proposed LT1FBR contains 5 key provisions for surface water and ground water under the direct influence of surface water (GWUDI) systems serving fewer than 10,000 people: A treatment technique requiring a 2-log (99 percent) *Cryptosporidium* removal requirement; strengthened combined filter effluent turbidity performance standards and new individual filter turbidity provisions; disinfection benchmark provisions to assure continued microbial protection is provided while facilities take the necessary steps to comply with new disinfection byproduct standards; inclusion of *Cryptosporidium* in the definition of GWUDI and in the watershed control requirements for unfiltered public water systems; and requirements for covers on new finished water reservoirs.

Today's proposed LT1FBR contains three key provisions for all conventional and direct filtration systems which recycle and use surface water or GWUDI: A provision requiring recycle flows to be introduced prior to the point of primary coagulant addition; a requirement for systems meeting criteria to perform a one-time self assessment of their recycle practice and consult with their primacy agency to address and correct high risk recycle operations; and a requirement for direct filtration systems to provide information to the State on their current recycle practice.

The Agency believes implementing the provisions contained in today's proposal will improve public health protection in two fundamental ways. First, the provisions will reduce the level of *Cryptosporidium* in filtered finished drinking water supplies through improvements in filtration and recycle practice resulting in a reduced likelihood of outbreaks of cryptosporidiosis. Second, the filtration provisions are expected to increase the level of protection from exposure to other pathogens (*i.e. Giardia* or other waterborne bacterial or viral pathogens). It is also important to note that while today's proposed rule contains new provisions which in some cases strengthen or modify requirements of the 1989 Surface Water Treatment Rule, each public water system must continue to comply with the current rules while new microbial and disinfectants/disinfection byproducts rules are being developed. In conjunction with the Maximum Contaminant Level Goal (MCLG) established in the Interim Enhanced Surface Water Treatment Rule, the Agency developed a treatment technique in lieu of a Maximum Contaminant Level (MCL) for *Cryptosporidium* because it is not economically and technologically feasible to accurately ascertain the level of *Cryptosporidium* using current analytical methods.

DATES: The Agency requests comments on today's proposal. Comments must be received or post-marked by midnight June 9, 2000. Comments received after this date may not be considered in decision making on the proposed rule.

ADDRESSES: Send written comments on today's proposed rule to the LT1FBR Comment Clerk: Water Docket MC 410, W–99–10, Environmental Protection Agency 401 M Street, S.W., Washington, DC 20460. Please submit an original and three copies of comments and enclosures (including references).

Those who comment and want EPA to acknowledge receipt of their comments must enclose a self-addressed stamped envelope. No facsimiles (faxes) will be accepted. Comments may also be submitted electronically to ow-docket@epamail.epa.gov. For additional information on submitting electronic comments see Supplementary Information Section.

Public comments on today's proposal, other major supporting documents, and a copy of the index to the public docket for this rulemaking are available for review at EPA's Office of Water Docket: 401 M Street, SW., Rm. EB57, Washington, DC 20460 from 9:00 a.m. to 4:00 p.m., Eastern Time, Monday through Friday, excluding legal holidays. For access to docket materials or to schedule an appointment please call (202) 260–3027.

FOR FURTHER INFORMATION CONTACT: Technical inquiries on the rule should be directed to Jeffery Robichaud at 401 M Street, SW., MC4607, Washington, DC 20460 or (202) 260–2568. For general information contact the Safe Drinking Water Hotline, Telephone (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding federal holidays, from 9:00 a.m. to 5:30 p.m. Eastern Time.

SUPPLEMENTARY INFORMATION: Entities potentially regulated by the LT1FBR are public water systems (PWSs) that use surface water or ground water under the direct influence of surface water (GWUDI). The recycle control provisions are applicable to all PWSs using surface water or GWUDI, regardless of the population served. All other provisions of the LT1FBR are only applicable to PWSs serving under 10,000 people. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Public Water Systems that use surface water or ground water under the direct influence of surface water.
State, Local, Tribal or Federal Governments.	Public Water Systems that use surface water or ground water under the direct influence of surface water.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the LT1FBR. This table lists the types of entities that EPA is now aware could potentially be regulated by this rule. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of public water system in § 141.3 of the Code of Federal Regulations and applicability criteria in §§ 141.76 and 141.501 of today's proposal. If you have questions regarding the applicability of the LT1FBR to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT**.

Submitting Comments

Send an original and three copies of your comments and enclosures (including references) to W–99–10 Comment Clerk, Water Docket (MC4101), USEPA, 401 M Street, SW., Washington, D.C. 20460. Comments must be received or post-marked by midnight June 9, 2000. Note that the Agency is not soliciting comment on, nor will it respond to, comments on previously published regulatory language that is included in this document to ease the reader's understanding of the proposed language.

To ensure that EPA can read, understand and therefore properly respond to comments, the Agency would prefer that commenters cite, where possible, the paragraph(s) or sections in the proposed rule or supporting documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed.

Electronic Comments

Comments may also be submitted electronically to ow-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII, WP5.1, WP6.1 or WP8 file avoiding the use of special characters and form of encryption. Electronic comments must be identified by the docket number W–99–10. Comments and data will also be accepted on disks in WP 5.1, 6.1, 8 or ASCII file format. Electronic comments on this document may be filed online at many Federal Depository Libraries.

The record for this rulemaking has been established under docket number W–99–10, and includes supporting documentation as well as printed, paper versions of electronic comments. The record is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays at the Water Docket, EB 57, USEPA Headquarters, 401 M Street, SW., Washington, D.C. For access to docket materials, please call (202) 260–3027 to schedule an appointment.

List of Abbreviations Used in This Document

ASCE American Society of Civil Engineers
ASDWA Association of State Drinking Water Administrators
ASTM American Society for Testing Materials
AWWA American Water Works Association
AWWARF American Water Works Association Research Foundation
°C Degrees Centigrade
CCP Composite Correction Program
CDC Centers for Disease Control
CFE Combined Filter Effluent
CFR Code of Federal Regulations
COI Cost of Illness
CPE Comprehensive Performance Evaluation
CT The Residual Concentration of Disinfectant (mg/L) Multiplied by the Contact Time (in minutes)
CTA Comprehensive Technical Assistance
CWSS Community Water System Survey
DBPs Disinfection Byproducts
DBPR Disinfectants/Disinfection Byproducts Rule
ESWTR Enhanced Surface Water Treatment Rule
FACA Federal Advisory Committee Act
GAC Granular Activated Carbon
GAO Government Accounting Office
GWUDI Ground Water Under the Direct Influence of Surface Water
HAA5 Haloacetic acids (Monochloroacetic, Dichloroacetic, Trichloroacetic, Monobromoacetic and Dibromoacetic Acids)
HPC Heterotropic Plate Count
hrs Hours
ICR Information Collection Rule
IESWTR Interim Enhanced Surface Water Treatment Rule
IFA Immunofluorescence Assay
Log Inactivation Logarithm of (N_o/N_T)
Log Logarithm (common, base 10)
LTESWTR Long Term Enhanced Surface Water Treatment Rule
LT1FBR Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule
MCL Maximum Contaminant Level
MCLG Maximum Contaminant Level Goal
MGD Million Gallons per Day
M-DBP Microbial and Disinfectants/Disinfection Byproducts
MPA Microscopic Particulate Analysis
NODA Notice of Data Availability
NPDWR National Primary Drinking Water Regulation
N_T The Concentration of Surviving Microorganisms at Time T
NTTAA National Technology Transfer and Advancement Act
NTU Nephelometric Turbidity Unit
PE Performance Evaluation
PWS Public Water System
Reg. Neg. Regulatory Negotiation
RIA Regulatory Impact Analysis
RFA Regulatory Flexibility Act
RSD Relative Standard Deviation
SAB Science Advisory Board
SDWA Safe Drinking Water Act
SWTR Surface Water Treatment Rule
TC Total Coliforms
TCR Total Coliform Rule
TTHM Total Trihalomethanes
TWG Technical Work Group
TWS Transient Non-Community Water System
UMRA Unfunded Mandates Reform Act
URCIS Unregulated Contaminant Information System
x log removal Reduction to $1/10^x$ of original concentration

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I. Introduction and Background

A. Statutory Requirements and Legal Authority

The Safe Drinking Water Act (SDWA or the Act), as amended in 1986, requires U.S. Environmental Protection Agency (EPA) to publish a maximum contaminant level goal (MCLG) for each contaminant which, in the judgement of the EPA Administrator, ''may have any adverse effect on the health of persons and which is known or anticipated to occur in public water systems' (Section 1412(b)(3)(A)). MCLGs are to be set at a level at which ''no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety'' (Section 1412(b)(4)).

The Act was again amended in August 1996, resulting in the renumbering and augmentation of certain sections with additional statutory language. New sections were added establishing new drinking water requirements. These modifications are outlined below.

The Act requires EPA to publish a National Primary Drinking Water Regulation (NPDWR) that specifies either a maximum contaminant level (MCL) or treatment technique (Sections 1401(1) and 1412(a)(3)) at the same time it publishes an MCLG, which is a non-enforceable health goal. EPA is authorized to promulgate a NPDWR ''that requires the use of a treatment technique in lieu of establishing an MCL,'' if the Agency finds that ''it is not economically or technologically feasible to ascertain the level of the contaminant.'' EPA's general authority to set MCLGs and NPDWRs applies to contaminants that may ''have an adverse effect on the health of persons,'' that are ''known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern,'' and for which ''in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems'' (SDWA Section 1412(b)(1)(A)).

The 1996 amendments, also require EPA, when proposing a NPDWR that includes an MCL or treatment technique, to publish and seek public comment on an analysis of health risk reduction and cost impacts. EPA is required to take into consideration the effects of contaminants upon sensitive subpopulations (i.e., infants, children, pregnant women, the elderly, and individuals with a history of serious illness), and other relevant factors (Section 1412(b)(3)(C)).

The amendments established a number of regulatory deadlines, including schedules for a Stage 1 Disinfection Byproduct Rule (DBPR), an Interim Enhanced Surface Water Treatment Rule (IESWTR), a Long Term Final Enhanced Surface Water Treatment Rule (LTESWTR), and a Stage 2 DBPR (Section 1412(b)(2)(C)). To provide additional time for systems serving fewer than 10,000 people to comply with the IESWTR provisions and also ensure these systems implement Stage 1 DBPR and the IESWTR provisions simultaneously, the Agency split the IESWTR into two rules: the IESWR and the LT1ESWTR. The Act as amended also requires EPA to promulgate regulations to ''govern'' the recycle of filter backwash within the treatment process of public utilities (Section 1412(b)(14)).

Under 1412(b)(4)(E)(ii), EPA must develop a Small System Technology List for the LT1FBR. The filtration technologies listed in the Small System Compliance Technology List for the Surface Water Treatment Rule and Total Coliform Rule (EPA–815–R–98–001, September 1998) are also the technologies which would achieve compliance with the provisions of the LT1FBR. EPA will develop a separate list for the LT1FBR as new technologies become available.

Although the Act permits small system variances for compliance with a requirement of a national primary drinking water regulation which specifies a maximum contaminant level or treatment technique, Section 1415(e)(6)(B) of SDWA, excludes variances for any national primary drinking water regulation for a microbial contaminant or an indicator or treatment technique for a microbial contaminant. LT1FBR requires treatment techniques to control *Cryptosporidium* (a microbial contaminant), and as such systems governed by the LT1FBR are ineligible for variances.

Finally, as part of the 1996 SDWA Amendments, recordkeeping requirements were modified to apply to every person who is subject to a requirement of this title or who is a grantee (Section 1445(a)(1)(A)). Such persons are required to establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation.

B. Existing Regulations and Stakeholder Involvement

1. 1979 Total Trihalomethane Rule

In November 1979 (44 FR 68624) (EPA, 1979) EPA set an interim MCL for total trihalomethanes (TTHM—the sum of chloroform, bromoform, bromodichloromethane, dibromochloromethane) of 0.10 mg/l as an annual average. Compliance is defined on the basis of a running annual average of quarterly averages for four samples taken in the distribution system. The value for each sample is the sum of the measured concentrations of chloroform, bromodichloromethane, dibromochloromethane and bromoform.

The interim TTHM standard applies to community water systems using surface water and/or ground water serving at least 10,000 people that add a disinfectant to the drinking water during any part of the treatment process. At their discretion, States may extend coverage to smaller PWSs; however, most States have not exercised this option. The Stage 1 DBPR (as discussed later) contains updated TTHM requirements.

2. Total Coliform Rule

The Total Coliform Rule (TCR) (54 FR 27544, June 29, 1989) (EPA, 1989a) applies to all public water systems. The TCR sets compliance with the Maximum Contaminant Level (MCL) for total coliforms (TC) as follows. For systems that collect 40 or more samples per month, no more than 5 percent of the samples may be TC-positive; for those that collect fewer than 40 samples, no more than one sample may be TC-positive. If a system has a TC-positive sample, it must test that sample for the presence of fecal coliforms or *E. coli*. The system must also collect a set of repeat samples, and analyze for TC (and fecal coliform or *E. coli* within 24 hours of the first TC-positive sample).

In addition, any fecal coliform-positive repeat sample, *E-coli.*-positive repeat sample, or any total-coliform-positive repeat sample following a fecal coliform-positive or *E-coli*-positive routine sample constitutes an acute violation of the MCL for total coliforms. If a system exceeds the MCL, it must notify the public using mandatory language developed by the EPA. The required monitoring frequency for a system depends on the number of people served and ranges from 480 samples per month for the largest systems to once annually for the smallest systems. All systems must have a written plan identifying where samples are to be collected.

The TCR also requires an on-site inspection (referred to as a sanitary survey) every 5 years for each system that collects fewer than five samples per month. This requirement is extended to every 10 years for non-community systems using only protected and disinfected ground water.

3. Surface Water Treatment Rule

Under the Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (EPA, 1989b), EPA set maximum contaminant level goals of zero for *Giardia lamblia*, viruses, and *Legionella* and promulgated regulatory requirements for all PWSs using surface water sources or ground water sources under the direct influence of surface water. The SWTR includes treatment technique requirements for filtered and unfiltered systems that are intended to protect against the adverse health effects of exposure to *Giardia* lamblia, viruses, and *Legionella,* as well as many other pathogenic organisms. Briefly, those requirements include (1) Requirements for maintenance of a disinfectant residual in the distribution system; (2) removal and/or inactivation of 3 log (99.9 percent) for *Giardia* and 4 log (99.99 percent) for viruses; (3) combined filter effluent turbidity performance standard of 5 nephelometric turbidity units (NTU) as a maximum and 0.5 NTU at the 95th percentile monthly, based on 4-hour monitoring for treatment plants using conventional treatment or direct filtration (with separate standards for other filtration technologies); and (4) watershed protection and other requirements for unfiltered systems. Systems seeking to avoid filtration were required to meet avoidance criteria and obtain avoidance determination by December 30, 1991, otherwise filtration must have been provided by June 29, 1993. For systems properly avoiding filtration, later failures to meet avoidance criteria triggered a requirement that filtration be provided within 18 months.

4. Information Collection Rule

The Information Collection Rule (ICR), which was promulgated on May 14, 1996 (61 FR 24354) (EPA, 1996) applied to large public water systems serving populations of 100,000 or more. A more limited set of ICR requirements pertain to ground water systems serving between 50,000 and 100,000 people. About 300 PWSs operating 500 treatment plants were involved with the extensive ICR data collection. Under the ICR, these PWSs monitored for water quality factors affecting disinfection byproduct (DBP) formation and DBPs within the treatment plant and in the distribution system on a monthly basis for 18 months. In addition, PWSs were required to provide treatment train schematics, operating data and source water occurrence data for bacteria, viruses, and protozoa. Finally, a subset of PWSs performed treatment studies, using either granular activated carbon (GAC) or membrane processes, to evaluate DBP precursor removal and control of DBPs. Monitoring for treatment study applicability began in September 1996. The remaining occurrence monitoring began in July 1997 and concluded in December 1998.

The purpose of the ICR was to collect occurrence and treatment information to help evaluate the need for possible changes to the current microbial requirements and existing microbial treatment practices, and to help evaluate the need for future regulation of disinfectants and disinfection byproducts (DBPs). The ICR will provide EPA with additional information on the national occurrence in drinking water of (1) chemical byproducts that form when disinfectants used for microbial control react with naturally occurring compounds already present in source water; and (2) disease-causing microorganisms, including *Cryptosporidium*, *Giardia*, and viruses. Analysis of ICR data is not expected to be completed in the time frame necessary for inclusion in the LT1FBR, however if the data is available and has been quality controlled and peer reviewed during the necessary time frame, EPA will consider the datat as it refines its analysis for the final rule.

The ICR also required PWSs to provide engineering data on how they currently control for such contaminants. The ICR monthly sampling data will also provide information on the quality of the recycle waters via monthly monitoring (for 18 months) of pH, alkalinity, turbidity, temperature, calcium and total hardness, TOC, UV_{254}, bromide, ammonia, and disinfectant residual (if disinfectant is used). This data will provide some indication of the treatability of the water, the extent to which contaminant concentration effects may occur, and the potential for contribution to DBP formation. However, sampling to determine the occurrence of pathogens in recycle waters was not performed.

5. Interim Enhanced Surface Water Treatment Rule

Public water systems serving 10,000 or more people that use surface water or ground water under the direct influence of surface water (GWUDI) are required to comply with the IESWTR (63 FR 69477, December 16, 1998) (EPA, 1998a) by December of 2001. The purposes of the IESWTR are to improve control of microbial pathogens, specifically the protozoan *Cryptosporidium*, and address risk trade-offs between pathogens and disinfection byproducts. Key provisions established by the rule include: a Maximum Contaminant Level Goal (MCLG) of zero for *Cryptosporidium*; 2-log (99 percent) *Cryptosporidium* removal requirements for systems that filter; strengthened combined filter effluent turbidity performance standards of 1.0 NTU as a maximum and 0.3 NTU at the 95th percentile monthly, based on 4-hour monitoring for treatment plants using conventional treatment or direct filtration; requirements for individual filter turbidity monitoring; disinfection benchmark provisions to assess the level of microbial protection provided as facilities take the necessary steps to comply with new disinfection byproduct standards; inclusion of *Cryptosporidium* in the definition of GWUDI and in the watershed control requirements for unfiltered public water systems; requirements for covers on new finished water reservoirs; and sanitary surveys for all surface water systems regardless of size.

6. Stage 1 Disinfectants and Disinfection Byproduct Rule

The Stage 1 DBPR applies to all PWSs that are community water systems (CWSs) or nontransient noncommunity water systems (NTNCWs) that treat their water with a chemical disinfectant for either primary or residual treatment. In addition, certain requirements for chlorine dioxide apply to transient noncommunity water systems (TNCWSs). The Stage 1 DBPR (EPA, 1998c) was published at the same time as the IESWTR (63 FR 69477, December 16, 1998) (EPA, 1998a). Surface water and GWUDI systems serving at least 10,000 persons are required to comply with the Stage 1 Disinfectants and Disinfection Byproducts Rule by December 2001. Ground water systems and surface water and GWUDI systems serving fewer than 10,000 must comply with the Stage 1 Disinfectants and Disinfection Byproducts Rule by December 2003.

The Stage 1 DBPR finalizes maximum residual disinfectant level goals (MRDLGs) for chlorine, chloramines, and chlorine dioxide; MCLGs for four trihalomethanes (chloroform, bromodichloromethane, dibromochloromethane, and bromoform), two haloacetic acids (dichloroacetic acid and trichloroacetic acid), bromate, and chlorite; and NPDWRs for three disinfectants (chlorine, chloramines, and chlorine dioxide), two groups of organic disinfection byproducts TTHMs and HAA5 and two inorganic disinfection byproducts, chlorite and bromate. The NPDWRs consist of maximum residual disinfectant levels (MRDLs) or maximum contaminant levels (MCLs) or treatment techniques for these disinfectants and their byproducts. The NPDWRs also include monitoring, reporting, and public notification requirements for these compounds. The Stage 1 DBPR includes the best available technologies (BATs) upon which the MRDLs and MCLs are based. EPA believes the implementation of the Stage 1 DBPR will reduce the levels of disinfectants and disinfection byproducts in drinking water supplies. The Agency believes the rule will provide public health protection for an additional 20 million households that were not previously covered by drinking water rules for disinfection byproducts.

7. Stakeholder Involvement

EPA conducted two stakeholder meetings to solicit feedback and information from the regulated community and other concerned stakeholders on issues relating to today's proposed rule. The first meeting was held July 22 and 23, 1998 in Lakewood, Colorado. EPA presented potential regulatory components for the LT1FBR. Breakout sessions with stakeholders were held to generate feedback on the regulatory provisions being considered and to solicit feedback on next steps for rule development and stakeholder involvement. Additionally, information was presented summarizing ongoing research and data gathering activities regarding the recycle of filter backwash. The presentations generated useful discussion and provided substantial feedback to EPA regarding technical issues, stakeholder concerns, and possible regulatory options (EPA 1999k). The second stakeholder meeting was held in Dallas, Texas on March 3 and 4, 1999. EPA presented new analyses, summaries of current research, and revised regulatory options and data collected since the July stakeholder meeting. Regional perspectives on turbidity and disinfection benchmarking components were also discussed with presentations from EPA Region VI and the Texas Natural Resources Conservation Commission. Four break-out sessions were extremely useful and generated a wide range of information, issues, and technical input from a diverse group of stakeholders (EPA 1999j).

The Agency utilized the feedback received during these two stakeholder meetings in developing today's proposed rule. EPA also mailed a draft version of the preamble for today's proposed rule to the attendees of these meetings. Several of the options which are presented today represent modifications suggested by stakeholders.

II. Public Health Risk

The purpose of this section is to discuss the health risk associated with pathogens, particularly *Cryptosporidium*, in surface waters and GWUDI. More detailed information about such pathogens and other contaminants of concern may be found in an EPA criteria document for *Giardia* (EPA 1998d), three EPA criteria documents for viruses (EPA, 1985; 1999a; 1999b), the *Cryptosporidium* and *Giardia* Occurrence Assessment for the Interim Enhanced Surface Water Treatment Rule (EPA, 1998b) and the LT1FBR Occurrence and Assessment Document (EPA 1999c). EPA requests comment on today's proposed rule, the information supporting the proposal, and the potential impact of proposed regulatory provisions on public health risk.

A. Introduction

In 1990, EPA's Science Advisory Board (SAB), an independent panel of experts established by Congress, cited drinking water contamination as one of the most important environmental risks and indicated that disease-causing microbial contaminants (i.e., bacteria, protozoa and viruses) are probably the greatest remaining health risk management challenge for drinking water suppliers (EPA/SAB, 1990). Information on the number of waterborne disease outbreaks from the U.S. Centers for Disease Control and Prevention (CDC) underscores this concern. CDC indicates that, between 1980 and 1996, 401 waterborne disease outbreaks were reported, with over 750,000 associated cases of disease. During this period, a number of agents were implicated as the cause, including protozoa, viruses and bacteria.

Waterborne disease caused by *Cryptosporidium* is of particular concern, as it is difficult to inactivate *Cryptosporidium* oocysts with standard disinfection practices (unlike pathogens such as viruses and bacteria), and there is currently no therapeutic treatment for cryptosporidiosis (unlike giardiasis). Because *Cryptosporidium* is not generally inactivated in systems using standard disinfection practices, the control of *Cryptosporidium* is dependent on physical removal processes (e.g., filtration).

The filter effluent turbidity limits specified under the SWTR were created to remove large parasite cysts such as *Giardia* and did not specifically control for smaller *Cryptosporidium* oocysts. In addition, filter backwash water recycling practices such as adding recycled water to the treatment train after primary coagulant addition may overwhelm the plant and harm efforts to control *Giardia lamblia, Cryptosporidium*, and emerging pathogens. Despite filtration and disinfection, *Cryptosporidium* oocysts have been found in filtered drinking water (LeChevallier, et al., 1991a; EPA, 1999c), and many of the individuals affected by waterborne disease outbreaks caused by *Cryptosporidium* were served by filtered surface water supplies (Solo-Gabriele and Neumeister, 1996). Surface water systems that filter and disinfect may still be vulnerable to *Cryptosporidium*, depending on the source water quality and treatment effectiveness. EPA believes that today's proposal, however, will ensure that drinking water treatment is operating efficiently to control *Cryptosporidium* (see Sections IV.A and IV.D) and other microbiological contaminants of concern (*e.g., Giardia*).

In order to assess the public health risk associated with consumption of surface water or GWUDI from PWSs, EPA has evaluated information and conducted analysis in four important areas discussed in the following paragraphs. These areas are: (1) The health effects of cryptosporidiosis; (2) cryptosporidiosis waterborne disease outbreak data; (3) *Cryptosporidium* occurrence data from raw surface water, raw GWUDI, finished water, and recycle stream studies; and (4) an assessment of the current baseline surface water treatment required by existing regulations.

B. Health Effects of Cryptosporidiosis and Sources and Transmission of Cryptosporidium

Waterborne diseases are usually acute (*i.e.,* sudden onset and typically lasting a short time in healthy people), and most waterborne pathogens cause gastrointestinal illness, with diarrhea, abdominal discomfort, nausea, vomiting, and/or other symptoms. Some waterborne pathogens cause or are associated with more serious disorders such as hepatitis, gastric cancer, peptic ulcers, myocarditis, swollen lymph glands, meningitis, encephalitis, and many other diseases. Cryptosporidiosis is a protozoal infection that usually causes 7–14 days of diarrhea with possibly a low-grade fever, nausea, and abdominal cramps in healthy individuals (Juranek, 1995). Unlike giardiasis for which effective antibiotic therapy is available, an antibiotic treatment for cryptosporidiosis does not exist (Framm and Soave, 1997).

There are several species of *Cryptosporidium* which have been identified, including *C. baileyi* and *C. meleagridis* (bird host); *C. muris* (mouse host); *C. nasorum* (fish host), *C. parvum* (mammalian host), and *C. serpentis* (snake host). *Cryptosporidium* parvum was first recognized as a human pathogen in 1976 (Juranek, 1995). Recently, both the human and cattle types of *C. parvum* have been found in healthy individuals, and these types, *C. felis*, and a dog type have been found in immunocompromised individuals (Pieniazek et al., 1999). Transmission of cryptosporidiosis often occurs through the ingestion of infective *Cryptosporidium* oocysts from feces-contaminated food or water, but may also result from direct or indirect contact with infected persons or mammals (Casemore, 1990; Cordell and Addiss, 1994). Dupont, et. al., 1995, found through a human feeding study that a low dose of *C. parvum* is sufficient to cause infection in healthy adults (Dupont et. al., 1995). Animal agriculture as a nonpoint source of *C. parvum* has been implicated as the source of contamination for the 1993 outbreak in Milwaukee, Wisconsin, the largest outbreak of waterborne disease in the history of the United States (Walker et al., 1998). Other sources of *C. parvum* include discharges from municipal wastewater treatment facilities and drainage from slaughterhouses. In addition, rainfall appears to increase the concentration of *Cryptosporidium* in surface water, documented in a study by Atherholt, et al. (1998).

There is evidence that an immune response to *Cryptosporidium* exists, but the degree and duration of this immunity is not well characterized (Fayer and Ungar, 1986). Recent work conducted by Chappell, *et al.* (1999) indicates that individuals with evidence of prior exposure to *Cryptosporidium parvum* have demonstrated immunity to low doses of oocysts (approximately 500 oocysts). The investigators found the 50 percent infectious dose for previously exposed individuals (possessing a pre-existing blood serum antibody) to be 1,880 oocysts compared to 132 oocysts for individuals without prior exposure, and individuals with prior exposure who became infected shed fewer oocysts. Because of this type of immune response, symptomatic infection in communities exposed to chronic low levels of oocysts will primarily be observed in newcomers (*e.g.,* visitors, young children) (Frost *et al.*, 1997; Okhuysen *et al.*, 1998).

Sensitive populations are more likely to become infected and ill, and gastrointestinal illness among this population may be chronic. These sensitive populations include children, especially the very young; the elderly; pregnant women; and the immunocompromised (Gerba *et al.*, 1996; Fayer and Ungar, 1986; EPA 1998e). This sensitive segment represents almost 20 percent of the population in the U.S. (Gerba *et al.*, 1996). EPA is particularly concerned about the exposure of severely immunocompromised persons to *Cryptosporidium* in drinking water, because the severity and duration of illness is often greater in immunocompromised persons than in healthy individuals, and it may be fatal among this population. For instance, a follow-up study of the 1993 Milwaukee, Wisconsin, waterborne disease outbreak reported that at least 50 *Cryptosporidium*-associated deaths occurred among the severely immunocompromised (Hoxie *et al.*, 1997).

Cases of illness from cryptosporidiosis were rarely reported until 1982, when the disease became prevalent due to the AIDS epidemic (Current, 1983). As laboratory diagnostic techniques improved during subsequent years, outbreaks among immunocompetent persons were recognized as well. Over the last several years there have been a number of documented waterborne cryptosporidiosis outbreaks in the U.S., United Kingdom, Canada and other countries (Rose, 1997, Craun *et al.*, 1998).

C. Waterborne Disease Outbreaks in the United States

The occurrence of outbreaks of waterborne gastrointestinal infections, including cryptosporidiosis, may be much greater than suggested by reported surveillance data (Craun and Calderon 1996). The CDC–EPA, and the Council of State and Territorial Epidemiologists have maintained a collaborative surveillance program for collection and periodic reporting of data on waterborne disease outbreaks since 1971. The CDC database and biennial CDC-EPA surveillance summaries include data reported voluntarily by the States on the incidence and prevalence of waterborne illnesses. However, the following information demonstrates why the reported surveillance data may under-report actual outbreaks.

The U.S. National Research Council strongly suggests that the number of identified and reported outbreaks in the CDC database (both for surface and ground waters) represents a small percentage of actual waterborne disease outbreaks National Research Council, 1997; Bennett *et al.*, 1987). In practice, most waterborne outbreaks in community water systems are not recognized until a sizable proportion of the population is ill (Perz *et al.*)

Healthy adults with cryptosporidiosis may not suffer severe symptoms from the disease; therefore, infected individuals may not seek medical assistance, and their cases are subsequently not reported. Even if infected individuals consult a physician, *Cryptosporidium* may not be identified by routine diagnostic tests for gastroenteritis and, therefore, tends to be under-reported in the general population (Juranek 1995). Such obstacles to outbreak reporting indicate that the incidence of disease and outbreaks of cryptosporidiosis may be much higher than officially reported by the CDC.

The CDC database is based upon responses to a voluntary and confidential survey that is completed by State and local public health officials. CDC defines a waterborne disease outbreak as occurring when at least two persons experience a similar illness after ingesting water (Kramer *et al.*, 1996). Cryptosporidiosis water system outbreak data from the CDC database appear in Table II.1 and Table II.2.

Table II.1 illustrates the reported number of waterborne disease outbreaks in U.S. community, noncommunity, and individual drinking water systems between 1971 and 1996. According to the CDC–EPA database, a total of 652 outbreaks and 572,829 cases of illnesses were reported between 1971 and 1996 (see Table II–1). The total number of outbreaks reported includes outbreaks resulting from protozoan contamination, virus contamination, bacterial contamination, chemical contamination, and unknown factors.

TABLE II.1.—COMPARISON OF OUTBREAKS AND OUTBREAK-RELATED ILLNESSES FROM GROUND WATER AND SURFACE WATER FOR THE PERIOD 1971–1996 [1]

Water source	Total outbreaks [2]	Cases of [2] illnesses	Outbreaks in CWSs	Outbreaks in NCWSs
Ground	371 (57%)	90,815 (16%).	113	258
Surface	223 (34%)	471,375 (82%).	148	43
Other	58 (9%)	10,639 (2%).	30	19

TABLE II.1.—COMPARISON OF OUTBREAKS AND OUTBREAK-RELATED ILLNESSES FROM GROUND WATER AND SURFACE WATER FOR THE PERIOD 1971–1996 [1]—Continued

Water source	Total outbreaks [2]	Cases of [2] illnesses	Outbreaks in CWSs	Outbreaks in NCWSs
All Systems [3]	652 (100%).	572,829 (100%).	291	320

[1] Craun and Calderon, 1994, CDC, 1998.
[2] Includes outbreaks in CWSs + NCWSs + Private wells.

Epidemiological investigations of outbreaks in populations served by filtered systems have shown that treatment deficiencies have resulted in the plants' failure to remove contamination from the water. Sometimes operational deficiencies have been discovered only during post-outbreak investigations. Rose (1997) identified the following types of environmental and operating conditions commonly present in filtered surface water systems at the time cryptosporidiosis outbreaks have occurred:

- Improperly-installed, -operated, -maintained, or -interpreted monitoring Equipment (*e.g.*, turbidimeters);
- Inoperable flocculators, chemical injectors, or filters;
- Inadequate personnel response to failures of primary monitoring equipment;
- Filter backwash recycle;
- High concentrations of oocysts in source water with no mitigative barrier;
- Flushing of oocysts (by heavy rain or snow melt) from land surfaces upstream of the plant intakes; and
- Altered or suboptimal filtration during periods of high turbidity, with turbidity spikes detected in finished water.

From 1984 to 1994, there have been 19 reported outbreaks of cryptosporidiosis in the U.S. (Craun *et al.,* 1998). As mentioned previously, C. parvum was not identified as a human pathogen until 1976. Furthermore, cryptosporidiosis outbreaks were not reported in the U.S. prior to 1984. Ten of these cryptosporidiosis outbreaks have been documented in CWSs, NCWSs, and a private water system (Moore *et al.*, 1993; Kramer *et al.,* 1996; Levy *et al.*, 1998; ; Craun *et al.*, 1998). The remaining nine outbreaks were associated with recreational activities (Craun *et al.*, 1998). The cryptosporidiosis outbreaks in U.S. drinking water systems are presented in Table II.2.

TABLE II.2.—CRYPTOSPORIDIOSIS OUTBREAKS IN U.S. DRINKING WATER SYSTEMS

Year	Location and CWS, NCWS, or private	Cases of illness (estimated)	Source water	Treatment	Suspected cause
1984	Braun Station, TX, CWS.	117 (2,000)	Well	Chlorination	Sewage-contaminated well.
1987	Carrollton, GA, CWS	(13,000)	River	Conventional filtration/chlorination; inadequate backwashing of some filters.	Treatment deficiencies.
1991	Berks County, PA, NCWS.	(551)	Well	Chlorination	Ground water under the influence of surface water.
1992	Medford (Jackson County), OR, CWS.	(3,000; combined total for Jackson County and Talent, below).	Spring/River	Chlorination/package filtration plant.	Source not identified.
1992	Talent, OR, CWS	see Medford, OR	Spring/River	Chlorination/package filtration plant.	Treatment deficiencies.
1993	Milwaukee, WI, CWS	(403,000)	Lake	Conventional filtration	High source water contamination and treatment deficiencies.
1993	Yakima, WA, private	7	Well	N/A	Ground water under the influence of surface water.
1993	Cook County, MN, NCWS.	27	Lake	Filtered, chlorinated	Possible sewage backflow from toilet/septic tank.
1994	Clark County, NV, CWS.	103; many confirmed for cryptosporidiosis were HIV positive.	River/Lake	Prechlorination, filtration and post-filtration chlorination.	Source not identified.
1994	Walla Walla, WA, CWS.	134	Well	None reported	Sewage contamination.

Craun, *et al.,* 1998.

Six of the ten cryptosporidiosis outbreaks reported in Table II.2 originated from surface water or possibly GWUDI supplied by public drinking water systems serving fewer than 10,000 persons. The first outbreak (117 known cases, 2,000 estimated cases of illness), in Braun Station, Texas in 1984, was caused by sewage leaking into a ground water well suspected to be under the influence of surface water. A second outbreak in Pennsylvania in 1991 (551 estimated cases of illness), occurred at a well also under the influence of surface water. The third and fourth (multi-episodic) outbreaks took place in Jackson County, Oregon in 1992 (3,000 estimated cases of illness) and were linked to treatment deficiencies in the Talent, OR surface water system. A fifth outbreak (27 cases of illness) in Minnesota, in 1993, occurred at a resort supplied by lake water. Finally, a sixth outbreak (134 cases of illness) in Washington in 1994, occurred due to sewage-contaminated wells at a CWS.

Three of the ten outbreaks (Carollton, GA (1987); Talent, OR (1992); Milwaukee, WI (1993)) were caused by water supplied by water treatment plants where the recycle of filter backwash was implicated as a possible cause of the outbreak. In total, the nine outbreaks which have taken place in PWSs have caused an estimated 419,939 cases of illness. These outbreaks illustrate that when treatment in place is not operating optimally or when source water is highly contaminated, *Cryptosporidium* may enter the finished drinking water and infect drinking water consumers, ultimately resulting in waterborne disease outbreaks.

D. Source Water Occurrence Studies

Cryptosporidium is common in the environment (Rose, 1988; LeChevallier et al., 1991b). Runoff from unprotected watersheds allows the transport of these microorganisms from sources of oocysts (*e.g.,* untreated wastewater, agricultural runoff) to water bodies used as intake sites for drinking water treatment plants. If treatment operates inefficiently, oocysts may enter the finished water at levels of public health concern. A particular public health challenge is that simply increasing existing disinfection levels above those most commonly practiced for standard disinfectants (i.e., chlorine or chloramines) in the U.S. today does not appear to be an effective strategy for controlling *Cryptosporidium*.

Cryptosporidium oocysts have been detected in wastewater, pristine surface water, surface water receiving agricultural runoff or contaminated by sewage, ground water under the direct influence of surface water (GWUDI), water for recreational use, and drinking water (Rose 1997, Soave 1995). Over 25 environmental surveys have reported *Cryptosporidium* source water occurrence data from surface water or GWUDI (presented in Tables II.3 and II.4), which typically involved the collection of a few water samples from a number of sampling locations having different characteristics (e.g., polluted vs. pristine; lakes or reservoirs vs. rivers). Results are presented as oocysts per 100 liters, unless otherwise marked.

Each of the studies cited in Tables II.3 and II.4 presents *Cryptosporidium* source water occurrence information, including (where possible): (1) The number of samples collected; (2) the number of samples positive; and (3) both the means and ranges for the concentrations of *Cryptosporidium* detected (where available). However, the immunofluorescence assay (IFA) method and other *Cryptosporidium* detection methods are inaccurate and lack adequate precision. Current methods do not indicate the species of *Cryptosporidium* identified or whether the oocysts detected are viable or infectious (Frey et al., 1997). The methods for detecting *Cryptosporidium* were modeled from *Giardia* methods, therefore recovery of *Cryptosporidium* is deficient primarily because *Cryptosporidium* oocysts are more difficult to capture due to their size (*Cryptosporidium* oocysts are 4–6μθ≧m; *Giardia* cysts are 8–12μθ≧m). In addition, it is a challenge to recover *Cryptosporidium* oocysts from the filters when they are concentrated, due to the adhesive character of the organisms. Other potential limitations to the protozoan detection methods include: (1) Filters used to concentrate the water samples are easily clogged by debris from the water sample; (2) interference occurs between debris or particulates that fluoresce due to cross reactivity of antibodies, which results in false positive identifications; (3) it is difficult to view the structure of oocysts on the membrane filter or slide, resulting in false negative determinations; and (4) most methods require an advanced level of skill to be performed accurately.

Despite these limitations, the occurrence information generated from these studies demonstrates that *Cryptosporidium* occurs in source waters. The source waters for which EPA has compiled information include rivers, reservoirs, lakes, streams, raw water intakes, springs, wells under the influence of surface water and infiltration galleries. The most comprehensive study in scope and national representation (LeChevallier and Norton, 1995) will be described in further detail following Tables II.3 and II.4.

TABLE II.3.—SUMMARY OF SURFACE WATER SURVEY AND MONITORING DATA FOR CRYPTOSPORIDIUM OOCYSTS

Sample source	Number of samples (n)	Samples positive for *Cryptosporidium* (percent)[a]	Range of oocyst conc. (oocysts/100L)	Mean (oocysts/100L)	Reference
Rivers	25	100	200–11,200	2510	Ongerth and Stibbs 1987.
River	6	100	200–580,000	192,000(a)	Madore et al. 1987.
Reservoirs/rivers (polluted)	6	100	19–300	99(a)	Rose 1988.
Reservoir (pristine)	6	83	1–13	2(a)	Rose 1988.
Impacted river	11	100	200–11,200[b]	2,500(g)	Rose et al. 1988a[b].
Lake	20	71	0–2200	58(g)	Rose et al. 1988b[b].
Stream	19	74	0–24,000	109(g)	Rose et al. 1988b[b]
Raw water	85	87	7–48,400	270(g) detectable.	LeChevallier et al. 1991c.
River (pristine)	59	32	NR	29(g)	Rose et al. 1991.
River (polluted)	38	74	<0.1–4,400[b]	66(g)	Rose et al. 1991.
Lake/reservoir (pristine)	34	53	NR	9.3(g)	Rose et al. 1991.
Lake/reservoir (polluted)	24	58	<0.1–380[b]	103(g)	Rose et al. 1991.

TABLE II.3.—SUMMARY OF SURFACE WATER SURVEY AND MONITORING DATA FOR CRYPTOSPORIDIUM OOCYSTS—Continued

Sample source	Number of samples (n)	Samples positive for *Cryptosporidium* (percent)[a]	Range of oocyst conc. (oocysts/100L)	Mean (oocysts/100L)	Reference
River (all samples)	36	97	15–45 (pristine) 1000–6,350 (agricultural).	20 (pristine) 1,830 (agricultural).	Hansen and Ongerth 1991.
Protected drinking water supply (subset of all).	6	81	15–42	24(g)	Hansen and Ongerth 1991.
Pristine river, forestry area (subset of all).	6	100	46–697	162(g)	Hansen and Ongerth 1991.
River below rural community in forested area (subset of all).	6	100	54–360	107(g)	Hansen and Ongerth 1991.
River below dairy farming agricultural activities (subset of all).	6	100	330–6,350	1,072(g)	Hansen and Ongerth 1991.
Reservoirs	56	45	NR	NR	Consonery et al. 1992.
Streams	33	48	NR	NR	Consonery et al. 1992.
Rivers	37	51	NR	NR	Consonery et al. 1992.
Site 1—River source (high turbidity)	10	100	82–7,190	480	LeChevallier and Norton 1992.
Site 2—River source (moderate turbidity).	10	70	42–510	250	LeChevallier and Norton 1992.
Site 3—Reservoir source (low turbidity).	10	70	77–870	250	LeChevallier and Norton 1992.
Lakes	179	6	0–2,240	3.3 (median)	Archer et al. 1995.
Streams	210	6	0–2,000	7 (median)	Archer et al. 1995.
Finished water	262	13	0.29–57	33 (detectable)	LeChevallier and Norton 1995.
River/lake	262	52	6.5–6,510	240 (detectable)	LeChevallier and Norton 1995.
River/lake	147	20	30–980	200	LeChevallier et al. 1995.
River 1	15	73	0–2,230	188 (a) all samples 43 (g) detected.	States et al. 1995.
River 2	15	80	0–1,470	147 (a) all samples 61 (g) detected.	States et al. 1995.
Dairy farm stream	13	77	0–1,110	126 (a) all samples 55 (g) detected.	States et al. 1995.
Reservoir inlets	60	5	0.7–24	1.9(g) 1.6 (median).	LeChevallier et al. 1997b.
Reservoir outlets	60	12	1.2–107	6.1(g) 60 (median).	LeChevallier et al. 1997b.
River (polluted)	72	40	20–280	24(g)	LeChevallier et al. 1997a.
Source water	NR	24	1–5,390[c]	740(a)[c] 71(g)[c]	Swertfeger et al. 1997.
First flush (storm event)	20	35	0–41,700	NR	Stewart et al. 1997.
Grab (non-storm event)	21	19	0–650	NR	Stewart et al. 1997.
River 1	24	63	0–1,470	58(g)	States et al. 1997.
Stream by dairy farm	22	82	0–2,300	42(g)	States et al. 1997.
River 2 (at plant intake)	24	63	0–2,200	31(g)	States et al. 1997.
Reservoirs (unfiltered system)	NR	37–52[d]	15–43 (maxima)[d].	0.8–1.4[d]	Okun et al. 1997.
Raw water intakes	148	25	0.04–18	0.3	Consonery et al. 1997.
Raw water intakes (rural)	NR	NR	40–400	NR	Swiger et al. 1999.
Raw Water	100 plants	77	0.5–117	3(g)	McTigue, et al. 1998.
DE River, Winter	18	NR	NR	70 per 500L(g)	Atherholt, et al. 1998.
DE River, Spring	18	NR	NR	100 per 500L(g)	Atherholt, et al. 1998.
DE River, Summer	18	NR	NR	30 per 500L(g)	Atherholt, et al. 1998.
DE River, Fall	18	NR	NR	20 per 500L(g)	Atherholt, et al. 1998.

[a] Rounded to nearest percent.
[b] As cited in Lisle and Rose 1995.
[c] Based on presumptive oocyst count
[d] Combined monitoring results for multiple sites in large urban water supply.
[e] As cited in States et al. 1997.
(a) = arithmetic average.
(g) = geometric average.
NR = not reported, NA = not applicable.

TABLE II.4.—SUMMARY OF U.S. GWUDI MONITORING DATA FOR CRYPTOSPORIDIUM OOCYSTS

Sample source	Number of samples (n)	Samples positive for *Cryptosporidium* oocysts (percent)	Range of positive values (oocysts/100L)	Mean (oocysts/100L) [a]	Reference
Well	17 (6 wells)	(1 sample)	.085L	NA	Archer et al. 1995.
Ground water sources (all categories)	199 sites[b]	11[b]	0.002–0.45d	NR	Hancock et al. 1998.
Vertical wells (subcategory of above ground water sources).	149 sites[b]	5[b]	NR	NR	Hancock et al. 1998.
Springs (subcategory of above ground water sources).	35 sites[b]	20[b]	NR	NR	Hancock et al. 1998.
Infiltration galleries (subcategory of above ground water sources).	4 sites[b]	50[b]	NR	NR	Hancock et al. 1998.
Horizontal wells (subcategory of above ground water sources).	11 sites[b]	45[b]	NR	NR	Hancock et al. 1998.
Ground water	17	41.2	NR	NR	Rosen et al., 1996.
Ground water	18	5.6	.13	.13	Rose et al. 1991.
Springs	7 (4 springs)	57[b]	0.25–10	4	Rose et al. 1991.
Wells	5 sites	100	0.26–3	0.9	SAIC, 1997 [c]
Vertical well Lemont Well #4 (Center Co., PA, Aug. 1992).	6	66.7	NR	NR	Lee, 1993.

[a] Geometric mean reported unless otherwise indicated.
[b] Data are presented as the percentage of positive sites.
[c] Data included are confirmed positive samples not reported in Hancock, 1998.
NA = not applicable.
NR = not reported.

The LeChevallier and Norton (1995) study collected the most samples and repeat samples from the largest number of surface water plants nationally. LeChevallier and Norton conducted the study to determine the level of *Cryptosporidium* in surface water supplies and plant effluent water. In total, surface water sources for 72 treatment plants in 15 States and 2 Canadian provinces were sampled. Sixty-seven surface water locations were examined. The generated data set covered a two-year monitoring period (March, 1991 to January, 1993) which was combined with a previous set of data (October, 1988 to June, 1990) collected from most of the same set of systems to create a database containing five samples (IFA) per site or more for 94 percent of the 67 systems sampled. *Cryptosporidium* oocysts were detected in 135 (51.5 percent) of the 262 raw water samples collected between March 1991 and January 1993, while 87 percent of the 85 samples were positive during the survey period from October, 1988 to June, 1990. The geometric mean of detectable *Cryptosporidium* was 240 oocysts/100L, with a range from 6.5 to 6510 oocysts/100L. When the 1991–1993 results (n=262) were combined with the previous results (n=85), *Cryptosporidium* was detected in 60.2 percent of the samples. The authors hypothesize the origin of the decrease in detections in the second round of sampling to be most probably linked to fluctuating or declining source water concentrations of *Cryptosporidium* oocysts from the first reporting period to the second.

LeChevallier and Norton (1995) also detected *Cryptosporidium* oocysts in 35 of 262 plant effluent samples (13.4 percent) analyzed between 1991 and 1993. When detected, the oocyst levels averaged 3.3 oocysts/100 L (range = 0.29 to 57 oocysts/100 L). A summary of occurrence data for all samples in filtered effluents for the years 1988 to 1993 showed that 32 of the water treatment plants (45 percent) were consistently negative for *Cryptosporidium*; 24 plants (34 percent) were positive once; and 15 plants (21 percent) were positive for *Cryptosporidium* two or more times between 1988 to 1993. Forty-four of the plants (62 percent) were positive for *Giardia*, *Cryptosporidium*, or both at one time or another (LeChevallier and Norton 1995).

The oocyst recoveries and densities reported by LeChevallier and Norton (1995) are comparable to the results of another survey of treated, untreated, protected (pristine) and feces-contaminated (polluted) water supplies (Rose et al. 1991). Six of thirty-six samples (17 percent) taken from potable drinking water were positive for *Cryptosporidium*, and concentrations in these waters ranged from .5 to 1.7 oocysts/100L. In addition, a total of 188 surface water samples were analyzed from rivers, lakes, or springs in 17 States. The majority of surface water samples were obtained from Arizona, California, and Utah (126 samples in all), with others from eastern States (28 samples), northwestern States (14 samples), southern States (13 samples), midwestern States (6 samples), and Hawaii (1 sample). Arithmetic average oocyst concentrations ranged from less than 1 to 4,400 oocysts/100 L, depending on the type of water analyzed. *Cryptosporidium* oocysts were found in 55 percent of the surface water samples at an average concentration of 43 oocysts/100 L.

The LeChevallier and Norton (1995) study collected the most samples and repeat samples from the most surface water plants on a national level. Therefore, the data from this study were analyzed by EPA (EPA, 1998n) to generate a distribution of source water occurrence, presented in Table II.5.

TABLE II.5.—BASELINE EXPECTED NATIONAL SOURCE WATER CRYPTOSPORIDIUM DISTRIBUTIONS

Percentile	Source water concentration (oocysts/100L)
25	103
50	231
75	516
90	1064
95	1641
Mean	470
Standard Deviation	841

Although limited by the small number of samples per site (one to sixteen samples; most sites were sampled five times), the mean concentration at the 69 sites from the eastern and central U.S. seems to be represented by a lognormal distribution.

In addition to the source water data, several studies have detected *Cryptosporidium* oocysts in finished water. The results of these studies have been compiled in Table II.6.

TABLE II.6.—SUMMARY OF U.S. FINISHED WATER MONITORING DATA FOR CRYPTOSPORIDIUM OOCYSTS

Sample source	Number of samples (n)	Samples positive for *Cryptosporidium* (percent)	Range of oocyst conc. (oocysts/100L)	Mean (oocysts/100L)	Reference
Filtered water	82	27	0.1–48	1.5	LeChevallier et al. 1991a.
Finished water (unfiltered)	6	33	0.1–1.7	0.2	LeChevallier et al. 1992.
Finished water	262	13	0.29–57	33 (detectable).	LeChevallier and Norton 1995.
Finished water (clearwell)	14	14	NR	NR	Consonery et al. 1992.
Finished water (filter effluents)	118	26	NR	NR	Consonery et al. 1992.
Site 1—Filter effluent	10	70	1–4	NR	LeChevallier and Norton 1992.
Site 2—Filter effluent	10	10	0.5	NA	LeChevallier and Norton 1992.
Site 3—Filter effluent	10	10	2	NA	LeChevallier and Norton 1992.
Finished water	1,237	7	NR	NR	Rosen et al. 1996.
Filtered (non-storm event)	87	10	0–420	NR	Stewart et al. 1997a.
Finished water	24	**8 ***13	0–0.6	0.5 (g)	States et al. 1997.
Finished water	155	2.5	0.02–0.8	0.2	Consonery et al. 1997.
Finished water	100	15	0.04–0.08	0.08 (g)	McTigue, et al. 1998.

*Plants
**Confirmed
***Presumed

These studies show that despite some treatment in place, *Cryptosporidium* may still pass through the treatment plant and into finished water.

In general, oocysts are detected more frequently and in higher concentrations in rivers and streams than in lakes and reservoirs (LeChevallier *et al.*, 1991b; Rose *et al.*, 1988a,b). Madore *et al.* (1987) found high concentrations of oocysts in a river affected by agricultural runoff (5800 oocysts/L). Such concentrations are especially significant if the contaminant removal process (*e.g.*, sedimentation, filtration) of the treatment plant is not operating effectively. Oocysts may pass through to the finished water, as LeChevallier and Norton (1995) and several other researchers also found, and infect drinking water consumers.

E. Filter Backwash and Other Process Streams: Occurrence and Impact Studies

Pathogenic microorganisms are removed during the sedimentation and/or filtration processes in a water treatment plant. Recycle streams generated during treatment, such as spent filter backwash water, sedimentation basin sludge, or thickener supernatant are often returned to the treatment train. These recycle streams, therefore, may contain high concentrations of pathogens, including chlorine-resistant *Cryptosporidium* oocysts. Recycle can degrade the treatment process, especially when entering the treatment train after the rapid mix stage, by causing a chemical imbalance, hydraulic surge and potentially overwhelming the plant's filtration capacity with a large concentration of pathogens. High oocyst concentrations found in recycle waters can increase the risk of pathogens passing through the treatment plant into finished water.

AWWA has compiled issue papers on each of the following recycle streams: Spent filter backwash water, sedimentation basin solids, combined thickener supernatant, ion-exchange regenerate, membrane concentrate, lagoon decant, mechanical dewatering device concentrate, monofill leachate, sludge drying bed leachate, and small-volume streams (*e.g.*, floor, roof, lab drains) (Environmental Engineering & Technology, 1999). In addition, EPA compiled existing occurrence data on *Cryptosporidium* in recycle streams. Through these efforts, *Cryptosporidium* occurrence data has been found for three types of recycle streams: Spent filter backwash water, sedimentation basin solids, and thickener supernatant.

Nine studies have reported the occurrence of *Cryptosporidium* for these process streams. Each study's scope and results are presented in Table II.7, and brief narratives on each major study follow the table. Note that the results of the studies, if not presented in the published report as oocysts/100L, have been converted into oocysts/100L.

TABLE II.7.—CRYPTOSPORIDIUM OCCURRENCE IN FILTER BACKWASH AND OTHER RECYCLE STREAMS

Name/location of study	Number of samples (n)	Type of sample	Cyst/oocyst concentration	Number of treatment plants sampled	Reference
Drinking water treatment facilities.	2	backflush waters from rapid sand filters.	sample 1: 26,000 oocysts/gal (calc. as 686,900 oocysts/100L). sample 2: 92,000 oocysts/gal (calc as 2,430,600 oocysts/100L)	2	Rose et al. 1986.

TABLE II.7.—CRYPTOSPORIDIUM OCCURRENCE IN FILTER BACKWASH AND OTHER RECYCLE STREAMS—Continued

Name/location of study	Number of samples (n)	Type of sample	Cyst/oocyst concentration	Number of treatment plants sampled	Reference
Thames, U.K.,	not reported	backwash water from rapid sand filter.	Over 1,000,000 oocysts/100L in backwash water on 2/19/89. 100,000 oocysts/100L in supernatant from settlement tanks during the next few days	1	Colbourne 1989.
Potable water supplies in 17 States.	not reported	filter backwash from rapid sand filters (10 to 40 L sample vol.).	217 oocysts/ 100 L (geometric mean).	not reported	Rose et al. 1991.
Name/location not reported.	not reported	raw water initial backwash water	7 to 108 oocysts/100L detected at levels 57 to 61 times higher than in the raw water.	not reported not reported	LeChevallier et al. 1991c.
Bangor Water Treatment Plant (PA).	*Round 1:* 1 (8-hour composite).	raw water filter backwash supernatant recycle 6 oocysts/100L.	902 oocysts/100L.	141 oocysts/ 100L. 1	Cornwell and Lee 1993.
Round 2: 1 (8-hour composite).	raw water filter backwash supernatant recycle	140 oocysts/100L	850 oocysts/100L.	750 oocysts/ 100L. 1	Cornwell and Lee 1993.
Moshannon Valley Water Treatment Plant.	Round 1: 1 (8-hour composite).	raw water spent backwash supernatant recycle sludge 13 oocysts/ 100L.	16,613 oocysts/100L.	82 oocysts/ 100L.	2,642 oocysts/100L. 1 Cornwell and Lee 1993.
	Round 2: 1 (8-hour composite).	raw water supernatant recycle	20 oocysts/100L	420 oocysts/ 100L. 1	Cornwell and Lee 1993.
Plant "C"	11 samples using continuous flow centrifugation;.	39 samples using cartridge filters.	backwash water from rapid sand filters; samples collected from sedimentation basins during sedimentation phase of backwash water at depths of 1, 2, 3, and 3.3 m.	continuous flow: range 1 to 69 oocysts/100 L; 8 of 11 samples positive.	cartridge filters: ranges 0.8 to 252/100 L; 33 of 39 samples positive 1 Karanis et al. 1996.
Pittsburgh Drinking Water Treatment Plant.	24 (two years of monthly samples).	filter backwash	328 oocysts/ 100 L (geometric mean); (38 percent occurrence rate).	non-detect-13,158 oocysts/ 100L. 1	States et al. 1997.
"Plant Number 3"	not reported	raw water spent backwash	140 oocysts/100L	850 oocysts/ 100L.	not reported Cornwell 1997.
"Plant C" (see Karanis, et al., 1996).	12 50	raw water backwash water from rapid sand filters.	avg. 23.2 oocysts/100L (max. 109 oocysts/100L) in 8 of 12 samples.	avg. 22.1 oocysts/100L (max. 257 oocysts/ 100L) in 41 of 50 samples	1 Karanis et al 1998.
"Plant A"	1	rapid sand filter (sample taken 10 min. after start of backwashing).	150 oocysts/100L.		

The occurrence data available and reported are primarily for raw and recycle stream water. If filter backwash enters the treatment train as a slug load and disrupts the treatment process, it is possible its effects would not be readily seen in the finished water until several minutes or hours after returning the filter to service. In addition, the poor recovery efficiencies of the IFA *Cryptosporidium* detection method complicate measurements in dilute finished effluent waters.

As shown in Table II.7, the concentrations of oocysts in backwash water and other recycle streams are greater than the concentrations generally found in raw water. For example, four studies (Cornwell and Lee, 1993; States *et al.,* 1997; Rose *et al.,* 1986; and Colbourne, 1989) have reported *Cryptosporidium* oocyst concentrations in filter backwash water exceeding 10,000 oocysts/100L. Such concentrations illustrate that the treatment plant has been removing oocysts from the influent water during the sedimentation and/or filtration processes. As expected, the oocysts have concentrated on the filters and/or in the sedimentation basin sludge. Therefore, the recycling of such process streams (*e.g.,* filter backwash, thickener supernatant, sedimentation basin sludge) re-introduces high concentrations of oocysts to the drinking water treatment train.

Recycle can potentially return a significant number of oocysts to the treatment plant in a short amount of time, particularly if the recycle is returned to the treatment process without prior treatment, equalization, or some other type of hydraulic detention. In addition, Di Giovanni, *et al.* (1999) presented data indicating that viable oocysts have been detected in filter backwash samples using a cell culture/polymerase chain reaction (PCR) method. Cell culture is a test of the viability/infectivity of the oocysts, while PCR identified the cells infected by *C. parvum.* Although recovery by IFA was poor (6 to 8 percent for backwash samples), 9 filter backwash recycle samples were found to contain viable and infectious oocysts, and the infectious agent was determined to be more than 98 percent similar in structure to *C. parvum.* Should filter backwash recycle disrupt normal treatment operations or should treatment not function efficiently due to other deficiencies, high concentrations of potentially viable, infectious oocysts may pass through the plant into finished drinking water. The recycle stream occurrence studies presented in Table II.7 are described in further detail in the following sections.

Thames, U.K. Water Utilities Experience with Cryptosporidium, Colbourne (1989)

In response to a cryptosporidiosis outbreak reported in February of 1989, Thames Water undertook an investigation of pathogen concentrations within the Farmoor conventional treatment plant's treatment train, finished and raw waters. The investigation occurred over a two month period, from February to April 1989 and included sampling of settled filter backwash, the supernatant from spent filter backwash, raw water, and water sampled at the end of various Thames distribution points.

On February 19, 1989 at the start of the outbreak investigation, a concentration of approximately 1,000,000 oocysts/100L was detected in the filter backwash water. During the first few days of the following investigation, the supernatant of the settled backwash water contained approximately 100,000 oocysts/100L. At the peak of the outbreak, thirty percent of Thames' distribution system samples were positive for oocysts, and ranged in concentration from 0.2 to 7700 oocysts/100L. Raw reservoir water contained oocyst concentrations ranging from .2 to 1400 oocysts/100L. After washing the filters twice in 24 hours, no oocysts were found in the settled backwash waters. Thames, U.K. Water Utilities determined that a storm causing intense precipitation and runoff resulted in elevated levels of oocysts in the source water which led to the high concentrations of oocysts entering the plant and subsequently deposited on the filters and recycled as filter backwash.

Survey of Potable Water Supplies for Cryptosporidium and Giardia, Rose, et al., 1991

In this survey, Rose, *et al.,* collected 257 samples from 17 States from 1985 to 1988. The samples were collected on cartridge filters and analyzed using variations of the IFA method. The reported percent recovery for the method was 29 to 58 percent. Filter backwash samples were a subset of the 257, 10 to 40 L samples were collected from rapid sand filters.

Rose, *et al.* reported the geometric mean of the backwash samples at 217 *Cryptosporidium* oocysts/100L. This was the highest reported average *Cryptosporidium* concentration of any of the water types tested, which included polluted and pristine surface and ground water sources, drinking water sources in addition to filter backwash recycle water.

Giardia and Cryptosporidium in Water Supplies, LeChevallier, et al. (1991c)

LeChevallier *et al.* conducted a study to determine ''whether compliance with the SWTR would ensure control of *Giardia* in potable water supplies.'' Raw water and plant effluent samples were collected from 66 surface water treatment plants in 14 States and one Canadian province, although only selected sites were tested for *Cryptosporidium* oocysts in filter backwash and settled backwash water.

In the analysis of pathogen concentrations in the raw water and filter backwash water of the water treatment process, LeChevallier *et al.* (1991c) found very high oocyst levels in backwash water of utilities that had low raw water parasite concentrations. The pathogens were detected using a combined IFA method that the authors developed. *Cryptosporidium* levels in the initial backwash water were 57 to 61 times higher than in the raw water supplies. Raw water samples were found to contain from 7 to 108 oocysts/100L. LeChevallier *et al.* (1991c) also noted that when *Cryptosporidium* were detected in plant effluent samples (12 of 13 times), the organisms were also observed in the backwash samples. The study concluded that the consistency of these results shows that accumulation of parasites in the treatment filters (and subsequent release in the filter backwash recycle water) could be related to subsequent passage through treatment barriers.

Recycle Stream Effects on Water Treatment, Cornwell and Lee (1993, 1994)

The results described in Cornwell and Lee's 1993 American Water Works Association Research Foundation Report and 1994 Journal of the American Water Works Association article on the Bangor and Moshannon Valley, PA water treatment plants are consistent with the results of States *et al.* (1997). In total, Cornwell and Lee investigated eight water treatment plants, examining treatment efficiencies including several recycle streams and their impacts, and reporting a range of pathogen and other water quality data. All of the pathogen testing was conducted using the EPA IFA method refined by LeChevallier, *et al.* (1991c).

Cornwell and Lee (1993) conducted two rounds of sampling at both the Bangor and Moshannon plants, sampling the different recycle and treatment streams as eight-hour composites. They detected *Cryptosporidium* concentrations of over 16,500 *Cryptosporidium* oocysts/100L in the backwash water at an adsorption clarifier plant (Moshannon Valley) and over 850 *Cryptosporidium* oocysts/100L in backwash water from a direct filtration plant (Bangor). The parasite levels in the backwash samples were significantly higher than concentrations found in the raw source water, which contained *Cryptosporidium* oocyst concentrations of 13–20 oocysts/100L at the Moshannon Valley plant and 6–140 oocysts/100L at the Bangor plant.

In addition, Cornwell and Lee determined oocyst concentrations for two other recycle streams, combined thickener supernatant and sedimentation basin solids. The supernatant pathogen concentrations were reported at 141 *Cryptosporidium* oocysts/100L at the Bangor plant, and levels were reported at 82 to 420 oocysts/100L for the Moshannon plant in Rounds 1 and 2 of sampling, respectively. The sedimentation basin sludge was reported at 2,642 *Cryptosporidium* oocysts/100L in the clarifier sludge from the Moshannon Valley plant.

Giardia and Cryptosporidium in Backwash Water from Rapid Sand Filters Used for Drinking Water, Karanis et al. (1996) and Distribution and Removal of Giardia and Cryptosporidium in Water Supplies in Germany Karanis, et al. (1998)

Karanis *et al.* (1996 and 1998) conducted a four-year research study (samples collected from July, 1993–December, 1995) on the efficiency of *Cryptosporidium* removal by six different surface water treatment plants from Germany, all of which treat by conventional filtration. The method used was an IFA method dubbed the ''EPA method'', developed by Jakubowski and Ericksen, 1979.

Karanis et al. (1996) detected *Cryptosporidium* in 82 percent of the samples of backwash water from rapid sand filters of a water treatment plant (''Plant C'') supplied by small rivers. Eight out of 12 raw water samples tested were positive for *Cryptosporidium* (range of 0.8 to 109 oocysts/100L). Backwash water samples collected by continuous flow centrifugation were positive for *Cryptosporidium* in 8 of 11 samples (range of 1 to 69/100L). Of 39 samples collected using cartridge filters, 33 were positive for *Cryptosporidium* (range of 0.8 to 252/100L). The authors called attention to the high detection rate of *Cryptosporidium* in the backwash waters (82 percent) of Plant C and to the fact that the supernatant following sedimentation was not free from cysts and oocysts (Karanis et al. 1996).

In the 1998 publication, Karanis et al. compiled the data from the 1996 study with more backwash occurrence data collected from another treatment plant (''Plant A''). The filter backwash of Plant A was sampled 10 minutes after the start of backwashing, and the backwash water was found to contain 150 *Cryptosporidium* oocysts/100L.

Protozoa in River Water: Sources, Occurrence, and Treatment, States, et al. (1997)

Over a two year period (July, 1994-June, 1996), States et al. sampled monthly for *Cryptosporidium* in the raw, settled, filtered and filter backwash water at the Pittsburgh Drinking Water Treatment Plant, in order to gauge the efficiency of pathogen removal at the plant. States et al. identified several sources contributing oocysts to the influent water, including sewage plant effluent, combined sewer overflows, dairy farm streams, and recycling of backwash water. All pathogen sampling was conducted with the IFA method.

Cryptosporidium occurred in the raw Allegheny river water supplying the plant with a geometric mean of 31 oocysts/100L in 63 percent of samples collected, and ranged from non-detect to 2,333 oocysts/100L (see Table II.3 for source water information). Of the filter backwash samples, a geometric mean of 328 oocysts/100L was found at an occurrence rate of 38 percent of samples, with a range from non-detect to 13,158 oocysts/100L. The fact that the mean concentration of *Cryptosporidium* oocysts in backwash water can be substantially higher than the oocyst concentration in untreated river water suggests that recycling untreated filter backwash water can be a significant source of this parasite to water within the treatment process.

F. Summary and Conclusions

Cryptosporidiosis is a disease without a therapeutic cure, and its causative agent, *Cryptosporidium*, is resistant to chlorine disinfection. *Cryptosporidium* has been known to cause severe illness, especially in immunocompromised individuals, and can be fatal. Several waterborne cryptosporidiosis outbreaks have been reported, and it is likely that others have occurred but have gone unreported. *Cryptosporidium* has been detected in a wide range of source waters, documented in over 30 studies from the literature, and it has been found at levels of concern in filter backwash water and other recycle streams.

One of the key regulations EPA has developed and implemented to counter pathogens in drinking water is the SWTR (54 FR 27486, June 19, 1989). The SWTR requires that surface water systems have sufficient treatment to reduce the source water concentration of *Giardia* and viruses by at least 99.9 percent (3 log) and 99.99 percent (4 log), respectively. A shortcoming of the SWTR, however, is that the rule does not specifically control for *Cryptosporidium*. The first report of a recognized waterborne outbreak caused by *Cryptosporidium* was published during the development of the SWTR (D'Antonio et al. 1985).

In 1998, the Agency finalized the IESWTR that enhances the microbial pathogen protection provided by the SWTR for systems serving 10,000 or more persons. The IESWTR includes an MCLG of zero for *Cryptosporidium* and requires a minimum 2-log (99 percent) removal of *Cryptosporidium*, linked to enhanced combined filter effluent and individual filter turbidity control provisions.

Several provisions of today's proposed rule, the LT1FBR, are designed to address the concerns covered by the IESWTR, improving control of *Cryptosporidium* and other microbial contaminants, for the portion of the public served by small PWSs (i.e., serving less than 10,000 persons). The LT1FBR also addresses the concern that for all PWSs that practice recycling, *Cryptosporidium* (and other emerging pathogens resistant to standard disinfection practice) are reintroduced to the treatment process of PWSs by the recycle of spent filter backwash water, solids treatment residuals, and other process streams.

Insufficient treatment practices have been cited as the cause of several reported waterborne disease outbreaks (Rose, 1997). Rose (1997) also found that a reduction in turbidity is indicative of a more efficient filtration process. Therefore, the turbidity and filter monitoring requirements of today's proposed LT1FBR will ensure that the removal process necessary to protect the public from cryptosporidiosis is operating properly, and the recycle stream provisions will ensure that the treatment process is not disrupted or operating inefficiently. The LT1FBR requirements that address the potential for *Cryptosporidium* to enter the finished drinking water supply will be described in more detail in the following sections.

III. Baseline Information-Systems Potentially Affected By Today's Proposed Rule

EPA utilized the 1997 state-verified version of the Safe Drinking Water Information System (SDWIS) to develop the total universe of systems which utilize surface water or groundwater under the direct influence (GWUDI) as sources. This universe consists of 11,593 systems serving fewer than 10,000 persons, and 2,096 systems serving 10,000 or more persons. Given this initial baseline, the Agency developed estimates of the number of systems which would be affected by components of today's proposed rule by utilizing three primary sources: Safe Drinking Water Information Systems; Community Water Supply Survey; and Water: Stats. A brief overview of each of the data sources is described in the following paragraphs.

Safe Drinking Water Information System (SDWIS)

SDWIS contains information about PWSs including violations of EPA's regulations for safe drinking water. Pertinent information in this database includes system name and ID, population served, geographic location, type of source water, and type of treatment (if provided).

Community Water System Survey (CWSS)

EPA conducted the 1995 CWSS to obtain data to support its development and evaluation of drinking water regulations. The survey consisted of a stratified random sample of 3,700 water systems nationwide (surface water and groundwater). The survey asked 24 operational and 13 financial questions.

Water:/Stats (WaterStats)

WaterStats is an in-depth database of water utility information compiled by the American Water Works Association. The database consists of 898 utilities of all sizes and provides a variety of data including treatment information.

Information regarding estimates of the number of systems which may potentially be affected by specific components of today's proposed rule can be found in the discussion of each proposed rule component in Section IV.

IV. Discussion of Proposed LT1FBR Requirements

A. Enhanced Filtration Requirements

As discussed earlier in this preamble, one of the key objectives of today's proposed rule is ensuring that an adequate level of public health protection is maintained in order to minimize the risk associated with *Cryptosporidium*. While the current SWTR provides protection from viruses and *Giardia*, it does not specifically address *Cryptosporidium*, which has been linked to outbreaks resulting in over 420,000 cases of gastrointestinal illness in the 1990s (403,000 associated with the Milwaukee outbreak). Because of *Cryptosporidium*'s resistance to disinfection practices currently in place at small systems throughout the country, the Agency believes enhanced filtration requirements are necessary to improve control of this microbial pathogen.

In the IESWTR, the Agency utilized an approach consisting of three major components to address *Cryptosporidium* at plants serving populations of 10,000 or more. The first component required systems to achieve a 2 log removal of *Cryptosporidium*. The second component consisted of strengthened turbidity requirements for combined filter effluent. The third component required individual filter turbidity monitoring.

In today's proposed rule addressing systems serving fewer than 10,000 persons, the Agency is utilizing the same framework. Where appropriate, EPA has evaluated additional options in an effort to alleviate burden on small systems while still maintaining a comparable level of public health protection.

The following sections describe the overview and purpose of each of the rule components, relevant data utilized during development, the requirements of today's proposed rule (including consideration of additional options where appropriate), and a request for comment regarding each component.

1. Two Log *Cryptosporidium* Removal Requirement

a. Two Log Removal

i. Overview and Purpose

The 1998 IESWTR (63 FR 69477, December 16, 1998) establishes an MCLG of zero for *Cryptosporidium* in order to adequately protect public health. In conjunction with the MCLG, the IESWTR also established a treatment technique requiring 2 log *Cryptosporidium* removal for all surface water and GWUDI systems which filter and serve populations of 10,000 or more people, because it was not economically and technologically feasible to accurately ascertain the level of *Cryptosporidium* using current analytical methods. The Agency believes it is appropriate and necessary to extend this treatment technique of 2 log *Cryptosporidium* removal requirement to systems serving fewer than 10,000 people.

ii. Data

As detailed later in this section, EPA believes that the data and principles supporting requirements established for systems serving populations of 10,000 or more are also applicable to systems serving populations fewer than 10,000. The following section provides information and data regarding: (1) the estimated number of small systems subject to the proposed 2 log *Cryptosporidium* removal requirement; and (2) *Cryptosporidium* removal using various filtration technologies.

Estimate of the Number of Systems Subject to 2 log Cryptosporidium Removal Requirement

Using the baseline described in Section III of today's proposed rule, the Agency applied percentages of surface water and GWUDI systems which filter (taken from the 1995 CWSS) in order to develop an estimate of the number of systems which filter and serve fewer than 10,000 persons. This resulted in an estimated 9,133 surface water and GWUDI systems that filter which may be subject to the proposed removal requirement. Table IV.1 provides this estimate broken down by system size and type.

TABLE IV.1.—ESTIMATE OF SYSTEMS SUBJECT TO 2 LOG CRYPTOSPORIDIUM REMOVAL REQUIREMENT [a]

System type	Population served					
	<100	101–500	501–1K [b]	1K–3.3K [b]	3.3K–10K [b]	Total #Sys.
Community	888	1453	950	2022	1591	6903
Non Community	1099	374	78	64	35	1649
NTNC	214	204	82	64	17	581
Total	2201	2031	1110	2150	1643	[b] 9134b

[a] Numbers may not add due to rounding
[b] K = thousands

Cryptosporidium Removal Using Conventional and Direct Filtration

During development of the LT1FBR, the Agency reviewed the results of several studies that demonstrated the ability of conventional and direct filtration systems to achieve 2 log removal of *Cryptosporidium* at well operated plants achieving low turbidity levels. Table IV.2 provides key information from these studies. A brief description of each study follows the table.

TABLE IV.2.—CONVENTIONAL AND DIRECT FILTRATION REMOVAL STUDIES

Type of treatment	Log removal	Experimental design	Researcher
Conventional	*Cryptosporidium* 4.2–5.2	Pilot plants	Patania *et al.* 1995
	Giardia 4.1–5.1	Pilot plants	Patania *et al.* 1995
	Cryptosporidium 1.9–4.0	Pilot-scale plants	Nieminski/Ongerth 1995
	Giardia 2.2–3.9	Pilot-scale plants	Nieminski/Ongerth 1995
	Cryptosporidium 1.9–2.8	Full-scale plants	Nieminski/Ongerth 1995
	Giardia 2.8–3.7	Full-scale plants	Nieminski/Ongerth 1995
	Cryptosporidium 2.3–2.5	Full-scale plants	LeChevallier and Norton 1992
	Giardia 2.2–2.8	Full-scale plants	
	Cryptosporidium 2–3	Pilot plants	LeChevallier and Norton 1992
	Giardia and Crypto 1.5–2	Full-scale plant (operation considered not optimized).	Foundation for Water Research, Britain 1994
	Cryptosporidium 4.1–5.2	Pilot Plant (optimal treatment)	Kelley *et al.* 1995
	Cryptosporidium .2–1.7	Pilot Plant (suboptimal treatment)	Dugan *et al.* 1999
			Dugan *et al.* 1999
Direct filtration	*Cryptosporidium* 2.7–3.1	Pilot plants	Ongerth/Pecaroro 1995
	Giardia 3.1–3.5	Pilot plants	Ongerth/Pecaroro 1995
	Cryptosporidium 2.7–5.9	Pilot plants	Patania *et al.* 1995
	Giardia 3.4–5.0	Pilot plants	Patania *et al.* 1995
	Cryptosporidium 1.3–3.8	Pilot plants	Nieminski/Ongerth 1995
	Giardia 2.9–4.0	Pilot plants	Nieminski/Ongerth 1995
	Cryptosporidium 2–3	Pilot plants	West *et al.* 1994
Rapid Granular Filtration (alone).	*Cryptosporidium* 2.3–4.9	Pilot plant	Swertfeger *et al.*, 1998
	Giardia 2.7–5.4		

Patania, Nancy L, et al. 1995

This study consisted of four pilot studies which evaluated treatment variables for their impact on *Cryptosporidium* and *Giardia* removal efficiencies. Raw water turbidities in the study ranged between 0.2 and 13 NTU. When treatment conditions were optimized for turbidity and particle removal at four different sites, *Cryptosporidium* removal ranged from 2.7 to 5.9 log and *Giardia* removal ranged from 3.4 to 5.1 log during stable filter operation. The median turbidity removal was 1.4 log, whereas the median particle removal was 2 log. Median oocyst and cyst removal was 4.2 log. A filter effluent turbidity of 0.1 NTU or less resulted in the most effective cyst removal, up to 1 log greater than when filter effluent turbidities were greater than 0.1 NTU (within the 0.1 to 0.3 NTU range). *Cryptosporidium* removal rates of less than 2.0 log occurred at the end of the filtration cycle.

Nieminski, Eva C. and Ongerth, Jerry E. 1995

This 2-year study evaluated *Giardia* and *Cryptosporidium* cyst removal through direct and conventional filtration. The source water of the full scale plant had turbidities typically between 2.5 and 11 NTU with a maximum of 28 NTU. The source water of the pilot plant typically had turbidities of 4 NTU with a maximum of 23 NTU. For the pilot plant achieving filtered water turbidities between 0.1–0.2 NTU, *Cryptosporidium* removals averaged 3.0 log for conventional treatment and 3.0 log for direct filtration, while the respective *Giardia* removals averaged 3.4 log and 3.3 log. For the full scale plant achieving similar filtered water turbidities, *Cryptosporidium* removal averaged 2.25 log for conventional treatment and 2.8 log for direct filtration, while the respective *Giardia* removals averaged 3.3 log for conventional treatment and 3.9 log for direct filtration. Differences in performance between direct filtration and conventional treatment by the full scale plant were attributed to differences in source water quality during the filter runs.

Ongerth, Jerry E. and Pecaroro, J.P. 1995

A 1 gallon per minute (gpm) pilot scale water filtration plant was used to measure removal efficiencies of *Cryptosporidium* and *Giardia* using very low turbidity source waters (0.35 to 0.58 NTU). With optimal coagulation, 3 log removal for both pathogens were obtained. In one test run, where coagulation was intentionally sub-optimal, the removals were only 1.5 log for *Cryptosporidium* and 1.3 log for *Giardia*. This demonstrates the importance of proper coagulation for cyst removal even though the effluent turbidity was less than 0.5 NTU.

LeChevallier, Mark W. and Norton, William D. 1992

The purpose of this study was to evaluate the relationships among *Giardia*, *Cryptosporidium*, turbidity, and particle counts in raw water and filtered water effluent samples at three different systems. Source water turbidities ranged from less than 1 to 120 NTU. Removals of *Giardia* and *Cryptosporidium* (2.2 to 2.8 log) were slightly less than those reported by other researchers, possibly because full scale plants were studied under less ideal conditions than the pilot plants. The participating treatment plants operated within varying stages of treatment optimization. The median removal achieved was 2.5 log for *Cryptosporidium* and *Giardia.*

LeChevallier, Mark W.; Norton, William D.; and Lee, Raymond G. 1991b

This study evaluated removal efficiencies for *Giardia* and *Cryptosporidium* in 66 surface water treatment plants in 14 States and 1 Canadian province. Most of the utilities achieved between 2 and 2.5 log removals for both *Giardia* and *Cryptosporidium*. When no oocysts were detected in the finished water, occurrence levels were assumed at the detection limit for calculating removal efficiencies.

Foundation for Water Research 1994

This study evaluated *Cryptosporidium* removal efficiencies for several treatment processes (including conventional filtration) using a pilot plant and bench-scale testing. Raw water turbidity ranged from 1 to 30 NTU. *Cryptosporidium* oocyst removal was between 2 and 3 log using conventional filtration. Investigators concluded that any measure which reduced filter effluent turbidity should reduce risk from *Cryptosporidium*, and also showed the importance of selecting proper coagulants, dosages, and treatment pH. In addition to turbidity, increased color and dissolved metal ion coagulant concentration in the effluent are indicators of reduced efficiency of coagulation/flocculation and possible reduced oocysts removal efficiency.

Kelley, M.B. et al. 1995

This study evaluated two U.S. Army installation drinking water treatment systems for the removal of *Giardia* and *Cryptosporidium*. Protozoa removal was between 1.5 and 2 log. The authors speculated that this low *Cryptosporidium* removal efficiency occurred because the coagulation process was not optimized, although the finished water turbidity was less than 0.5 NTU.

West, Thomas; et al. 1994

This study evaluated the removal efficiency of *Cryptosporidium* through direct filtration using anthracite mono-media at filtration rates of 6 and 14 gpm/sq.ft. Raw water turbidity ranged from 0.3 to 0.7 NTU. Removal efficiencies for *Cryptosporidium* at both filtration rates were 2 log during filter ripening (despite turbidity exceeding 0.2 NTU), and 2 to 3 log for the stable filter run. Log removal declined significantly during particle breakthrough. When effluent turbidity was less than 0.1 NTU, removal typically exceeded 2 log. Log removals of *Cryptosporidium* generally exceeded that for particle removal.

Swertfeger et al., 1998

The Cincinnati Water Works conducted a 13 month pilot study to determine the optimum filtration media and depth of the media to replace media at its surface water treatment plant. The study investigated cyst and oocyst removal through filtration alone (excluding chemical addition, mixing, or sedimentation) and examined sand media, dual media, and deep dual media. Cyst and oocyst removal by each of the media designs was > 2.5 log by filtration alone.

Dugan et al., 1999

EPA conducted pilot scale experiments to assess the ability of conventional treatment to control *Cryptosporidium* oocysts under steady state conditions. The work was performed with a pilot plant designed to minimize flow rates and the number of oocysts required for spiking. With proper coagulation control, the conventional treatment process achieved at least 2 log removal of *Cryptosporidium*. In all cases where 2 log removal was not achieved, the plant also did not comply with the IESWTR filter effluent turbidity requirements.

All of the studies described above indicate that rapid granular filtration, when operated under appropriate coagulation conditions and optimized to achieve a filtered water turbidity level of less than 0.3 NTU, should achieve at least 2 log of *Cryptosporidium* removal. Removal rates vary widely, up to almost 6 log, depending upon water matrix conditions, filtered water turbidity effluent levels, and where and when removal efficiencies are measured within the filtration cycle. The highest log pathogen removal rates occurred in those pilot plants and systems which achieved very low finished water turbidities (less than 0.1 NTU). Other key points related to the studies include:

- As turbidity performance improves for treatment of a particular water, there tends to be greater removal of *Cryptosporidium*.
- Pilot plant study data in particular indicate high likelihood of achieving at least 2 log removal when plant operation is optimized to achieve low turbidity levels. Moreover, pilot studies represented in Table IV.2.a tend to be for low-turbidity waters, which are considered to be the most difficult to treat regarding particulate removal and associated protozoan removal.
- Because high removal rates were demonstrated in pilot studies using lower-turbidity source waters, it is likely that similar or higher removal rates can be achieved for higher-turbidity source waters.
- Determining *Cryptosporidium* removal in full-scale plants can be difficult due to the fact that data includes many non-detects in the finished water. In these cases, finished water concentration levels are assigned at the detection limit and are likely to result in over-estimation of oocysts in the finished water. This tends to under-estimate removal levels.
- Another factor that contributes to differences among the data is that some of the full-scale plant data comes from plants that are not optimized, but meet existing SWTR requirements. In such cases, oocyst removal may be less than 2 log. In those studies that indicate that full-scale plants are achieving greater than 2 log removal (LeChevallier studies in particular), the following characteristics pertain:

—Substantial numbers of filtered water measurements resulted in oocyst detections;

—Source water turbidity tended to be relatively high compared to some of the other studies; and

—A significant percentage of these systems were also achieving low filtered water turbidities, substantially less than 0.5 NTU.

- Removal of *Cryptosporidium* can vary significantly in the course of the filtration cycle (i.e., at the start-up and end of filter operations versus the stable period of operation).

Cryptosporidium Removal Using Slow Sand and Diatomaceous Earth Filtration

During development of the IESWTR, the Agency also evaluated several studies which demonstrated that slow sand and diatomaceous earth filtration were capable of achieving at least 2 log removal of *Cryptosporidium*. Table IV.3 provides key information from these studies. A brief description of each study follows the table.

TABLE IV.3.—SLOW SAND AND DIATOMACEOUS EARTH FILTRATION REMOVAL STUDIES

Type of treatment	Log removal	Experimental design	Researcher
Slow-sand filtration	Giardia & Cryptosporidium > 3	Pilot plant at 4.5 to 16.5°C.	Shuler and Ghosh 1991.
	Cryptosporidium 4.5	Full-scale plant	imms et. al. 1995.
Diatomaceous earth filtration.	Giardia & Cryptosporidium > 3	Pilot plant,	Shuler et. al. 1990.
	Cryptosporidium 3.3–6.68	Bench scale	Ongerth & Hutton, 1997.

Shuler and Ghosh 1991

This pilot study was conducted to evaluate the ability of slow sand filters to remove *Giardia*, *Cryptosporidium*, coliforms, and turbidity. The pilot study was conducted at Pennsylvania State University using a raw water source with a turbidity ranging from 0.2–0.4 NTU. Influent concentration of

Cryptosporidium oocysts during the pilot study ranged from 1,300 to 13,000 oocysts/gallon. Oocyst removal was shown to be greater than 4 log.

Timms et al 1995

This pilot study was conducted to evaluate the efficiency of slow sand filters at removing *Cryptosporidium*. A pilot plant was constructed of 1.13 m^2 in area and 0.5 m in depth with a filtration rate of 0.3m/h. The filter was run for 4–5 weeks before the experiment to ensure proper operation. *Cryptosporidium* oocysts were spiked to a concentration of 4,000/L. Results of the study indicated a 4.5 log removal of *Cryptosporidium* oocysts.

Shuler et al 1990

In this study, diatomaceous earth (DE) filtration was evaluated for removal of *Giardia*, *Cryptosporidium*, turbidity and coliform bacteria. The study used a 0.1m^2 pilot scale DE filter with three grades of diatomaceous earth (A, B, and C). The raw water turbidity varied between 0.1 and 1 NTU. Filter runs ranged from 2 days to 34 days. A greater than 3 log removal of *Cryptosporidium* was demonstrated in the 9 filter runs which made up the study.

Ongerth and Hutton, 1997

Bench scale studies were used to define basic characteristics of DE filtration as a function of DE grade and filtration rate. Three grades of DE were used in the tests. *Cryptosporidium* removal was measured by applying river water seeded with *Cryptosporidium* to Walton test filters. Tests were run for filtration rates of 1 and 2 gpm/sq ft. Each run was replicated 3 times. Approximately 6 logs reduction in the concentration of *Cryptosporidium* oocysts was expected under normal operating conditions.

Cryptosporidium Removal Using Alternative Filtration Technologies

EPA recognizes that systems serving fewer than 10,000 individuals employ a variety of filtration technologies other than those previously discussed. EPA collected information regarding several other popular treatment techniques in an effort to verify that these treatments were also technically capable of achieving a 2 log removal of *Cryptosporidium*. A brief discussion of these alternative technologies follows along with studies demonstrating effective *Cryptosporidium* removals.

Membrane Filtration

Membrane filtration (Reverse Osmosis, Nanofiltration, Ultrafiltration, and Microfiltration) relies upon pore size in order to remove particles from water. Membranes possess a pore size smaller than that of a *Cryptosporidium* oocyst, enabling them to achieve effective log removals. The smaller the pore size, the more effective the rate of removal. Typical pore sizes for each of the four types of membrane filtration are shown below:

- Microfiltration—1–0.1 microns (µm)
- Ultrafiltration—0.1–.01 (µm)
- Nanofiltration—.01–.001 (µm)
- Reverse Osmosis—<.001 (µm)

Bag Filtration

Bag filters are non-rigid, disposable, fabric filters where water flows from inside of the bag to the outside of the bag. One or more filter bags are contained within a pressure vessel designed to facilitate rapid change of the filter bags when the filtration capacity has been used up. Bag filters do not generally employ any chemical coagulation. The pore sizes in the filter bags designed for protozoa removal generally are small enough to remove protozoan cysts and oocysts but large enough that bacteria, viruses and fine colloidal clays would pass through. Bag filter studies have shown a significant range of results in the removal of *Cryptosporidium* oocysts (0.33–3.2 log). (Goodrich, 1995)

Cartridge Filtration

Cartridge filtration also relies on physical screening to remove particles from water. Typical cartridge filters are pressure filters with glass, fiber or ceramic membranes, or strings wrapped around a filter element housed in a pressure vessel (USEPA, 1997a).

The Agency evaluated several studies which demonstrate the ability of various alternative filtration technologies to achieve 2 log removal of *Cryptosporidium* (in several studies 2 log removal of 4–5 (µm) microspheres were used as a surrogate for *Cryptosporidium*). These studies demonstrate that 2 log removal was consistently achievable in all but bag filters. Table IV.4 provides key information from these studies. A brief description of each study follows:

TABLE IV.4.—ALTERNATIVE FILTRATION REMOVAL STUDIES

Type of treatment	Log removal	Experimental design	Researcher
Microfiltration	*Cryptosporidium* 4.2–4.9 log	Bench Scale	Jacangelo *et al.* 1997.
	Giardia 4.6–5.2 log		
	Cryptosporidium 6.0—7.0 log	Pilot Plant	
	Cryptosporidium 4.3—5.0 log	Pilot Plant	Drozd & Schartzbrod, 1997.
	Cryptosporidium 7.0–7.7 log	Bench Scale	Hirata & Hashimoto, 1998.
	Microspheres 3.57–3.71 log	Full Scale	Goodrich *et al.* 1995.
Ultrafiltration	*Cryptosporidium* 4.4—4.9 log	Bench Scale	Jacangelo *et al.* 1997.
	Giardia 4.7–5.2 log		
	Cryptosporidium 5.73–5.89 log	Bench Scale	Collins *et al.* 1996.
	Giardia 5.75–5.85 log		
	Cryptosporidium 7.1–7.4 log	Bench Scale	Hirata & Hashimoto, 1998.
	Cryptosporidium 3.5 log	pilot Plant	Lykins *et al.* 1994.
	Microspheres 3–4 log		
Reverse Osmosis	Cryptosporidium > 5.7 log	Pilot Scale	Adham *et al.* 1998
	Giardia > 5.7 log.		
Hybrid Membrane	Microspheres 4.18 log	Bench Scale	Goodrich et al. 1995
Bag Filtration	Microspheres .33–3.2 log	Pilot Plant	Goodrich et al. 1995
Cartridge filtration	Microspheres 3.52–3.68 log	Pilot Plant	Goodrich et al. 1995
	Particles (5–15 um) > 2 log	Bench Scale	Land, 1998.

Jacangelo et al., 1997

Bench scale and pilot plant tests were conducted with microfiltration and ultrafiltration filters (using six different membranes) in order to evaluate microorganism removal. Bench scale studies were conducted under worst case operating conditions (direct flow filtration at the maximum recommended transmembrane pressure using deionized water slightly buffered at pH 7). Log removal ranged from 4.7 to 5.2 log removal. Pilot plant results ranged from 6.0–7.0 log removal during worst-case operating conditions (*i.e.,* direct filtration immediately after backwashing at the maximum recommended operating transmembrane pressure).

Drozd and Schartzbrod, 1997

A pilot plant system was established to evaluate the removal of *Cryptosporidium* using crossflow microfiltration (.2 µm porosity). Results demonstrated *Cryptosporidium* log removals of 4.3 to greater than 5.5 with a corresponding mean filtrate turbidity of 0.25 NTU.

Collins et. al., 1996

This study consisted of bench scale testing of *Cryptosporidium* and *Giardia* log removals using an ultrafiltration system. Log removal of *Cryptosporidium* ranged from 5.73 to 5.89 log, while removal of *Giardia* ranged from 5.75 to 5.85 log.

Hirata & Hashimoto, 1998

Pilot scale testing using microfiltration (nominal pore size of .25 µm) and ultrafiltration (nominal cut-off molecular weight (MW) 13,000 daltons) was conducted to determine *Cryptosporidium* oocyst removal. Results conducted on the ultrafiltration units ranged from 7.1 to 7.5 logs of *Cryptosporidium* removal. Results of the microfiltration studies yielded log removals from 7.0 to 7.7 log.

Lykins et al., [1994]

An ultrafiltration system was evaluated for the removal of *Cryptosporidium* oocysts at the USEPA Test and Evaluation Facility in Cincinnati, Ohio. The filter run was just over 48 hours. A 3.5 log removal of *Cryptosporidium* oocysts was observed. Additionally, twenty-four experiments were performed using 4.5 µm polystyrene microspheres as a surrogate for *Cryptosporidium* because of a similar particle distribution. Log removal of microspheres ranged from 3 to 4 log.

Adham et al., 1998

This study was conducted to evaluate monitoring methods for membrane integrity. In addition to other activities, microbial challenge tests were conducted on reverse osmosis (RO) membranes to both determine log removals and evaluate system integrity. Log removal of *Cryptosporidium* and *Giardia* was >5.7 log in uncompromised conditions, and > 4.5 log in compromised conditions.

Goodrich et al., 1995

This study was conducted to evaluate removal efficiencies of three different bag filtration systems. Average filter pore size of the filters was 1 µm while surface area ranged from 35 to 47 sq ft. Bags were operated at 25, 50 and 100 percent of their maximum flow rate while spiked with 4.5 µm polystyrene microspheres (beads) as a surrogate for *Cryptosporidium*. Bead removal ranged from .33 to 3.2 log removal.

Goodrich et al 1995.

This study evaluated a cartridge filter with a 2 µm rating and 200 square feet of surface area for removal efficiency of *Cryptosporidium* sized particles. The filter was challenge tested with 4.5 µm polystyrene microspheres as a surrogate for *Cryptosporidium*. Flow was set at 25 gpm with 50 psi at the inlet. Results from two runs under the same conditions exhibited log removals of 3.52 and 3.68.

Land, 1998

An alternative technology demonstration test was conducted to evaluate the ability of a cartridge filter to achieve 2 log removal of particles in the 5 to 15 µm range. The cartridge achieved at least 2 log removal of the 5 to 25 µm particles 95 percent of the time up to a 20 psi pressure differential. The filter achieved at least 2 log removal of 5 to 15 µm particles up to 30-psi pressure differential.

While the studies above note that alternative filtration technologies have demonstrated in the lab the capability to achieve a 2 log removal of *Cryptosporidium*, the Agency believes that the proprietary nature of these technologies necessitates a more rigorous technology-specific determination be made. Given this issue, the Agency believes that its Environmental Technology Verification (ETV) Program can be utilized to verify the performance of innovative technologies. Managed by EPA's Office of Research and Development, ETV was created to substantially accelerate the entrance of new environmental technologies into the domestic and international marketplace. ETV consists of 12 pilot programs, one of which focuses on drinking water. The program contains a protocol for physical removal of microbiological and particulate contaminants, including test plans for bag and cartridge filters and membrane filters (NSF, 1999). These protocols can be utilized to determine whether a specific alternative technology can effectively achieve a 2 log removal of *Cryptosporidium*, and under what parameters that technology must be operated to ensure consistent levels of removal. Additional information on the ETV program can be found on the Agency's website at http://www.epa.gov/etv.

iii. Proposed Requirements

Today's proposed rule establishes a requirement for 2 log removal of *Cryptosporidium* for surface water and GWUDI systems serving fewer than 10,000 people that are required to filter under the SWTR. Compliance with the combined filter effluent turbidity requirements, as described later, ensures compliance with the 2 log removal requirement. The requirement for a 2 log removal of *Cryptosporidium* applies between a point where the raw water is not subject to recontamination by surface water runoff and a point downstream before or at the first customer.

iv. Request for Comments

EPA requests comment on the 2 log removal requirement as discussed. The Agency is also soliciting public comment and data on the ability of alternative filtration technologies to achieve 2 log *Cryptosporidium* removal.

2. Turbidity Requirements

a. Combined Filter Effluent

i. Overview and Purpose

In order to address concern with *Cryptosporidium*, EPA has analyzed log removal performance by well operated plants (as described in the previous section) as well as filter performance among small systems to develop an appropriate treatment technique requirement that assures an increased level of *Cryptosporidium* removal. In evaluating combined filter performance requirements, EPA considered the strengthened turbidity provisions within the IESWTR and evaluated whether these were appropriate for small systems as well.

ii. Data

In an effort to evaluate combined filter effluent (CFE) requirements, EPA collected data in several areas to supplement existing data, and address situations unique to smaller systems. This data includes:

- An estimate of the number of systems subject to the proposed strengthened turbidity requirements;
- Current turbidity levels at systems throughout the U.S. serving populations fewer than 10,000;
- The ability of package plants to meet strengthened turbidity standards; and
- The correlation between meeting CFE requirements and achieving 2 log removal of *Cryptosporidium*.

Estimate of the Number of Systems Subject to Strengthened CFE Turbidity Standards

Using the estimate of 9,134 systems which filter and serve fewer than 10,000 persons (as described in Section IV.A.1 of today's proposal), the Agency used the information contained within the CWSS database to estimate the number of systems which utilized specific types of filtration. The data was segregated based on the type of filtration utilized and the population size of the system. Percentages were derived for each of the following types of filtration:

- Conventional and Direct Filtration;
- Slow Sand Filtration;
- Diatomaceous Earth Filtration; and
- Alternative Filtration Technologies.

The percentages were applied to the estimate discussed in Section IV.A.1 of today's proposal for each of the respective population categories. Based on this analysis, the Agency estimates 5,896 conventional and direct filtration systems will be subject to the strengthened combined filter effluent turbidity standards. EPA estimates 1,756 systems utilize slow sand or diatomaceous earth filtration, and must continue to meet turbidity standards set forth in the SWTR. The remaining 1,482 systems are estimated to use alternative filtration technologies and will be required to meet turbidity standards as set forth by the State upon analysis of a 2 log *Cryptosporidium* demonstration conducted by the system.

Current Turbidity Levels

EPA has developed a data set which summarizes the historical turbidity performance of various filtration plants serving populations fewer than 10,000 (EPA, 1999d). The data set represents those systems that were in compliance with the turbidity requirements of the SWTR during all months being analyzed. The data set consists of 167 plants from 15 States. Table IV.5 provides information regarding the number of plants from each State. The data set includes plants representing each of the five population groups utilized in the CWSS (25–100, 101–500, 501–1,000, 1,001–3,300, and 3,301–10,000). The Agency has also received an additional data set from the State of California (EPA, 2000). This data has not been included in the assessments described below. The California data demonstrates similar results to the larger data set discussed below.

TABLE IV.5.—SUMMARY OF LT1FBR TURBIDITY DATA SET

State	Number of Plants
Alabama	1
California	1
Colorado	16
Illinois	13
Kansas	20
Louisiana	6
Minnesota	3
Montana	2
North Carolina	16
Ohio	4
Pennsylvania	27
South Carolina	16
Texas	23
Washington	17
West Virginia	2
Total	167

(EPA, 1999d)

This data was evaluated to assess the national impact of modifying existing turbidity requirements. The current performance of plants was assessed with respect to the number of months in which selected 95th percentile and maximum turbidity levels were met. The data show that approximately 88 percent of systems are also currently meeting the new requirements of a maximum turbidity limit of 1 NTU (Figure IV.1). With respect to the 95th percentile turbidity limit, roughly 46 percent of these systems are currently meeting the new requirement of 0.3 NTU (Figure IV.2) while approximately 70 percent meet this requirement 9 months out of the year. Estimates for systems needing to make changes to meet a turbidity performance limit of 0.3 NTU were based on the ability of systems currently to meet a 0.2 NTU. This assumption was intended to take into account a utility's concern with possible turbidity measurement error and to reflect the expectation that a number of utilities will attempt to achieve finished water turbidity levels below the regulatory performance level to assure compliance.

As depicted in Figure IV.1 and IV.2, the tighter turbidity performance standards for combined filter effluent in today's proposed rule reflect the actual, current performance many systems already achieve nationally. Revising the turbidity criteria effectively ensures that these systems continue to perform at their current level while also improving performance of a substantial number of systems that currently meet existing SWTR criteria, but operate at turbidity levels higher than proposed in today's rule.

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FIGURE IV.1

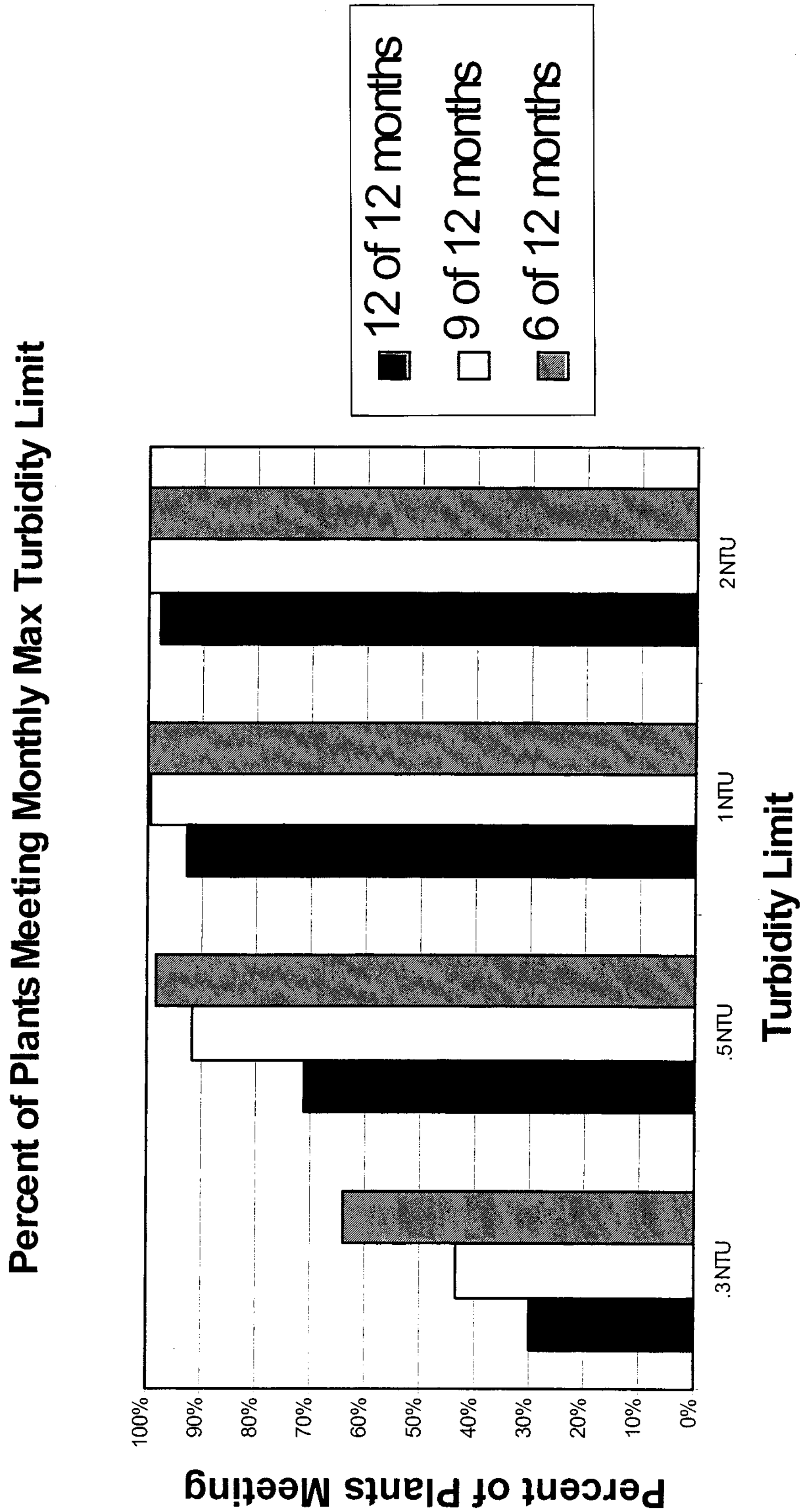
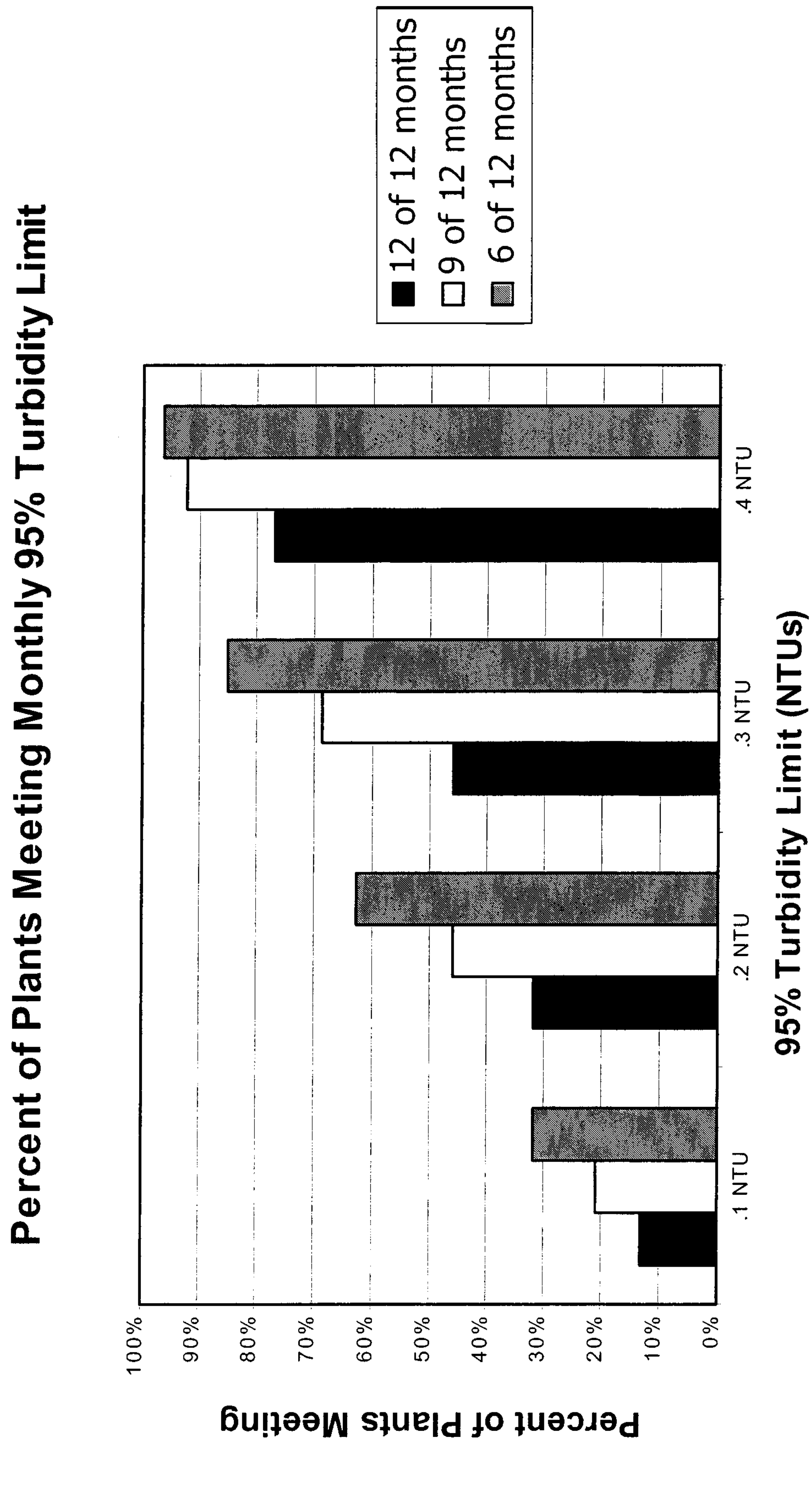

Percent of Plants Meeting Monthly Max Turbidity Limit
12 of 12 months
9 of 12 months
6 of 12 months
Percent of Plants Meeting
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
.3NTU
.5NTU
1NTU
2NTU
Turbidity Limit

FIGURE IV.2


Percent of Plants Meeting Monthly 95% Turbidity Limit
12 of 12 months
9 of 12 months
6 of 12 months
Percent of Plants Meeting
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
.1 NTU
.2 NTU
.3 NTU
.4 NTU
95% Turbidity Limit (NTUs)

Package Plants

During development of today's proposed rule, some stakeholders expressed concern regarding the ability of ''package plants'' to meet the proposed requirements. EPA evaluated these systems by gathering data from around the country. The information affirms the Agency's belief that package plants can and currently do meet the turbidity limits in today's proposed rule.

Package plants combine the processes of rapid mixing, flocculation, sedimentation and filtration (rapid sand, mixed or dual media filters) into a single package system. Package Filtration Plants are preconstructed, skid mounted and transported virtually assembled to the site. The use of tube settlers, plate settlers, or adsorption clarifiers in some Package Filtration Plants results in a compact size and more treatment capacity.

Package Filtration Plants are appropriate for treating water of a fairly consistent quality with low to moderate turbidity. Effective treatment of source waters containing high levels of or extreme variability in turbidity levels requires skilled operators and close operational attention. High turbidity or excessive color in the source water could require chemical dosages above the manufacturer's recommendations for the particular plant. Excessive turbidity levels may require presedimentation or a larger capacity plant. Specific design criteria of a typical package plant and operating and maintenance requirements can vary, but an example schematic is depicted in Figure IV.3.

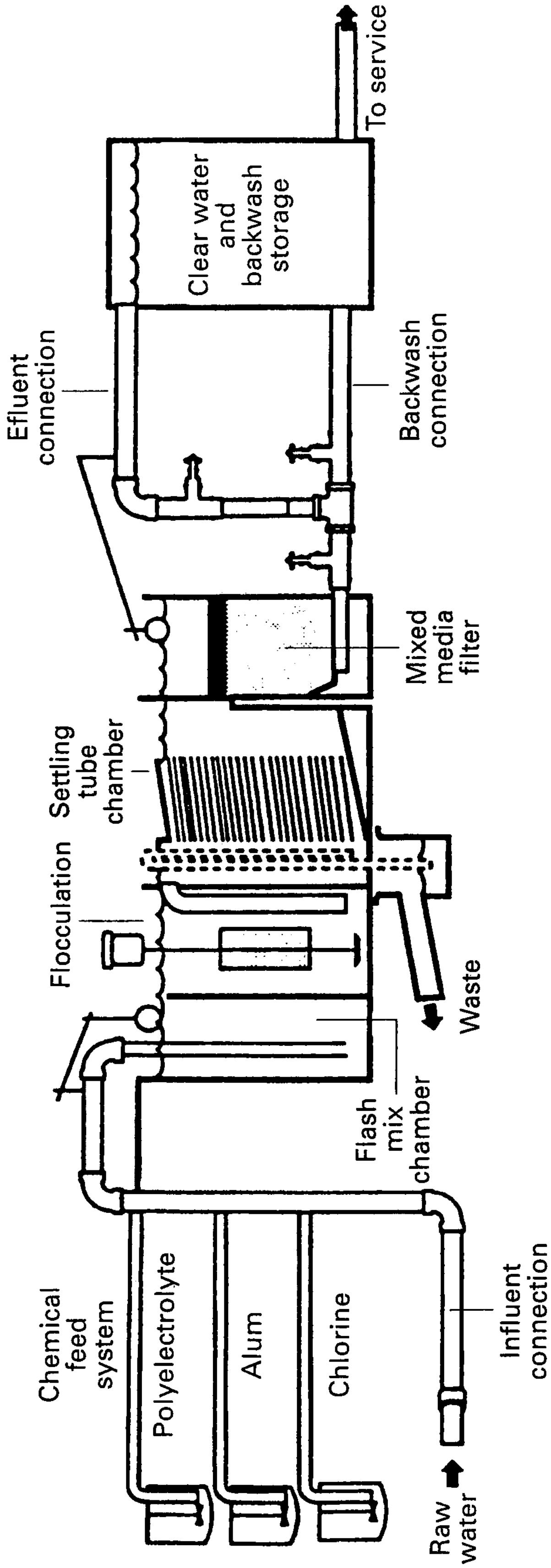


Figure IV.3 Example Package Plant Schematic

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The Agency believes that historic data show that package plants have a comparable ability to meet turbidity requirements as conventional or direct filtration systems.

A 1987 report of pilot testing using a trailer-mounted package plant system to treat raw water from Clear Lake in Lakeport, California demonstrates the ability of such systems to achieve low turbidity requirements. The raw water contained moderate to high turbidity (18 to 103 NTU). Finished water turbidities ranged from 0.07 to 0.11 NTU (EPA, 1987). Two previous studies (USEPA, 1980a,b and Cambell et al., 1995) also illustrate the ability of package systems throughout the country to meet historic turbidity performance criteria. These studies are described briefly:

Package Water Treatment Plant Performance Evaluation (USEPA, 1980a,b)

The Agency conducted a study of package water treatment systems which encompassed 36 plants in Kentucky, West Virginia, and Tennessee. Results from that study showed that the plants could provide water that met the existing turbidity limits established under the National Interim Primary Drinking Water Standards. Of the 31 plants at which turbidity measurements were made, 23 (75 percent) were found to be meeting existing standards. Of the 8 which did not meet requirements, one did not use chemical coagulants, and 6 operated less than four hours per day. (USEPA, 1980a, b)

Package Plants for Small Systems: A Field Study (Cambell et al, 1995)

This 1992 project evaluated the application of package plant technology to small communities across the U.S. The project team visited 48 facilities across the U.S. Of the 29 surface water and GWUDI systems, 21 (72 percent) had grab turbidity samples less than 0.5 NTU, the 95 percent limit which became effective in June of 1993. Twelve systems (41 percent) had values less than today's proposed 0.3 NTU 95 percent turbidity limit. (Cambell et al., 1995) It should be noted that today's rule requires compliance with turbidity limits based on 4 hour measurments.

The Agency recently evaluated Filter Plant Performance Evaluations (FPPEs) conducted by the State of Pennsylvania, in an effort to quantify the comparative abilities of package plants and conventional filtration systems to meet the required turbidity limits. The data set consisted of 100 FPPEs conducted at systems serving populations fewer than 10,000 (PADEP, 1999). Thirty-seven FPPEs were conducted at traditional conventional filtration systems while 37 were conducted at package plants or ''pre-engineered'' systems. The remaining 26 systems utilized other filtration technologies.

The FPPEs provided a rating of either acceptable or unacceptable as determined by the evaluation team. This rating was based on an assessment of the capability of individual unit processes to continuously provide an effective barrier to the passage of microorganisms. Specific performance goals were utilized to evaluate the performance of the system including the consistent ability to produce a finished water turbidity of less than 0.1 NTU, which is lower than the combined filter effluent turbidity requirement in today's proposed rule. Seventy-three percent of the traditional conventional filtration systems were rated acceptable and 89 percent of the package plants were rated acceptable.

The Agency also evaluated historic turbidity data graphs contained within each FPPE to provide a comparison of the ability of package plants and conventional systems to meet the 1 NTU max and 0.3 NTU 95 percent requirements that are contained in today's proposed rule. Sixty-seven percent of the conventional systems would meet today's proposed requirements while 74 percent of package systems in the data set would meet today's proposed requirements. The Agency believes that, when viewed alongside the aforementioned studies (USEPA, 1980a,b and Cambell et al., 1995), it is apparent that package systems have the ability to achieve more stringent turbidity limits.

Correlation Between CFE Requirements and 2-log Cryptosporidium Removal

Recent pilot scale experiments performed by the Agency assessed the ability of conventional treatment to control *Cryptosporidium* under steady state conditions. The work was performed with a pilot plant that was designed to minimize flow rates and as a result the number of oocyst required for continuous spiking. (Dugan et al. 1999)

Viable oocysts were fed into the plant influent at a concentration of 10^6/L for 36 to 60 hours. The removals of oocysts and the surrogate parameters turbidity, total particle counts and aerobic endospores were measured through sedimentation and filtration. There was a positive correlation between the log removals of oocysts and all surrogate parameters through the coagulation and settling process. With proper coagulation control, the conventional treatment process achieved the 2 log total *Cryptosporidium* removal required by the IESWTR. In all cases where 2 log total removal was not achieved, the plant also did not comply with the IESWTR's CFE turbidity requirements. Table IV.6 provides information on *Cryptosporidium* removals from this study.

TABLE IV.6.—LOG REMOVAL OF OOCYSTS (DUGAN ET AL. 1999)

Run	Log removal crypto	Exceeds CFE requirements
1	4.5	No.
2	5.2	No.
3	1.6	Yes, average CFE 2.1 NTU.
4	1.7	Yes, only 88% CFE under 0.3 NTU.
5	4.1	No.
6	5.1	No.
7	0.2	Yes, average CFE 0.5 NTU.
8	0.5	Yes, only 83% CFE under 0.3 NTU.
9	5.1	No.
10	4.8	No.

iii. Proposed Requirements

Today's proposed rule establishes combined filter effluent turbidity requirements which apply to all surface water and GWUDI systems which filter and serve populations fewer than 10,000. For conventional and direct filtration systems, the turbidity level of representative samples of a system's combined filter effluent water must be less than or equal to 0.3 NTU in at least 95 percent of the measurements taken each month. The turbidity level of representative samples of a system's filtered water must not exceed 1 NTU at any time.

For membrane filtration, (microfiltration, ultrafiltration, nanofiltration, and reverse osmosis) the Agency is proposing to require that the turbidity level of representative samples of a system's combined filter effluent water must be less than or equal to 0.3 NTU in at least 95 percent of the measurements taken each month. The turbidity level of representative samples of a system's filtered water must not exceed 1 NTU at any time. EPA included turbidity limits for membrane systems to allow such systems the ability to opt out of a possible costly demonstration of the ability to remove *Cryptosporidium*. The studies displayed previously in Table IV.4, demonstrate the ability of these technologies to achieve log-removals in excess of 2 log. In lieu of these turbidity limits, a public water system which utilizes membrane filtration may demonstrate to the State for purposes of membrane approval (using pilot plant studies or other means) that membrane filtration in combination with disinfection treatment consistently achieves 3 log removal and/or inactivation of *Giardia* lamblia cysts, 4 log removal and/or inactivation of viruses, and 2 log removal of *Cryptosporidium* oocysts. For each approval, the State will set turbidity performance requirements that the system must meet at least 95 percent of the time and that the system may not exceed at any time at a level that consistently achieves 3 log removal and/or inactivation of *Giardia* lamblia cysts, 4 log removal and/or inactivation of viruses, and 2 log removal of *Cryptosporidium* oocysts.

Systems utilizing slow sand or diatomaceous earth filtration must continue to meet the combined filter effluent limits established for these technologies under the SWTR (found in § 141.73 (b) and (c)). Namely, the turbidity level of representative samples of a system's filtered water must be less than or equal to 1 NTU in at least 95 percent of the measurements taken each month and the turbidity level of representative samples of a system's filtered water must at no time exceed 5 NTU.

For all other alternative filtration technologies (those other than conventional, direct, slow sand, diatomaceous earth, or membrane), public water systems must demonstrate to the State for purposes of approval (using pilot plant studies or other means), that the alternative filtration technology in combination with disinfection treatment, consistently achieves 3 log removal and/or inactivation of *Giardia* lamblia cysts, 4 log removal and/or inactivation of viruses, and 2 log removal of *Cryptosporidium* oocysts. For each approval, the State will set turbidity performance requirements that the system must meet at least 95 percent of the time and that the system may not exceed at any time at a level that consistently achieves 3 log removal and/or inactivation of *Giardia* lamblia cysts, 4 log removal and/or inactivation of viruses, and 2 log removal of *Cryptosporidium* oocysts.

iv. Request for Comments

EPA solicits comment on the proposal to require systems to meet the proposed combined filter effluent turbidity requirements. Additionally, EPA solicits comment on the following:

- The ability of package plants and/or other unique conventional and/or direct systems to meet the combined filter effluent requirements;
- Microbial attachment to particulate material or inert substances in water systems may have the effect of providing ''shelter'' to microbes by reducing their exposure to disinfectants (USEPA, 1999e). While inactivation of *Cryptosporidium* is not a consideration of this rule, should maximum combined filter effluent limits for slow sand and diatomaceous earth filtration systems be lowered to 1 or 2 NTU and/or 95th percentile requirements lowered to 0.3 NTU to minimize the ability of turbidity particles to ''shelter'' *Cryptosporidium* oocysts?
- Systems which practice enhanced coagulation may produce higher turbidity effluent because of the process. Should such systems be allowed to apply to the State for alternative exceedance levels similar to the provisions contained in the rule for systems which practice lime softening?
- Issues specific to small systems regarding the proposed combined filter effluent requirements;
- Establishment of turbidity limits for alternative filtration technologies;
- Allowance of a demonstration to establish site specific limits in lieu of generic turbidity limits, including components of such demonstration; and
- The number of small membrane systems employed throughout the country.

The Agency also requests comment on establishment of turbidity limits for membrane systems. While integrity of membranes provides the clearest understanding of the effectiveness of membranes, turbidity has been utilized as an indicator of performance (and corresponding *Cryptosporidium* log removal) for all filtration technologies. EPA solicits comment on modifying the requirements for membrane filters to meet integrity testing, as approved by the State and with a frequency approved by the State.

b. Individual Filter Turbidity

i. Overview and Purpose

During development of the IESWTR, it was recognized that performance of individual filters within a plant were of paramount importance to producing low-turbidity water. Two important concepts regarding individual filters were discussed. First, it was recognized that poor performance (and potential pathogen breakthrough) of one filter could be masked by optimal performance in other filters, with no discernable rise in combined filter effluent turbidity. Second, it was noted that individual filters are susceptible to turbidity spikes (of short duration) which would not be captured by four-hour combined filter effluent measurements. To address the shortcomings associated with individual filters, EPA established individual filter monitoring requirements in the IESWTR. For the reasons discussed below, the Agency believes it appropriate and necessary to extend individual filter monitoring requirements to systems serving populations fewer than 10,000 in the LT1FBR.

ii. Data

EPA believes that the support and underlying principles regarding the IESWTR individual filter monitoring requirements are also applicable for the LT1FBR. The Agency has estimated that 5,897 conventional and direct filtration systems will be subject to today's proposed individual filter turbidity requirements. Information regarding this estimate is found in Section IV.A.2.a of today's proposal. The Agency has analyzed information regarding turbidity spikes and filter masking which are presented next.

Turbidity Spikes

During a turbidity spike, significant amounts of particulate matter (including *Cryptosporidium* oocysts, if present) may pass through the filter. Various factors affect the duration and amplitude of filter spikes, including sudden changes to the flow rate through the filter, treatment of the filter backwash water, filter-to-waste capability, and site-specific water quality conditions. Recent experiments have suggest that surging has a significant effect on rapid sand filtration performance (Glasgow and Wheatley, 1998). An example filter profile depicting turbidity spikes is shown in Figure IV.4.

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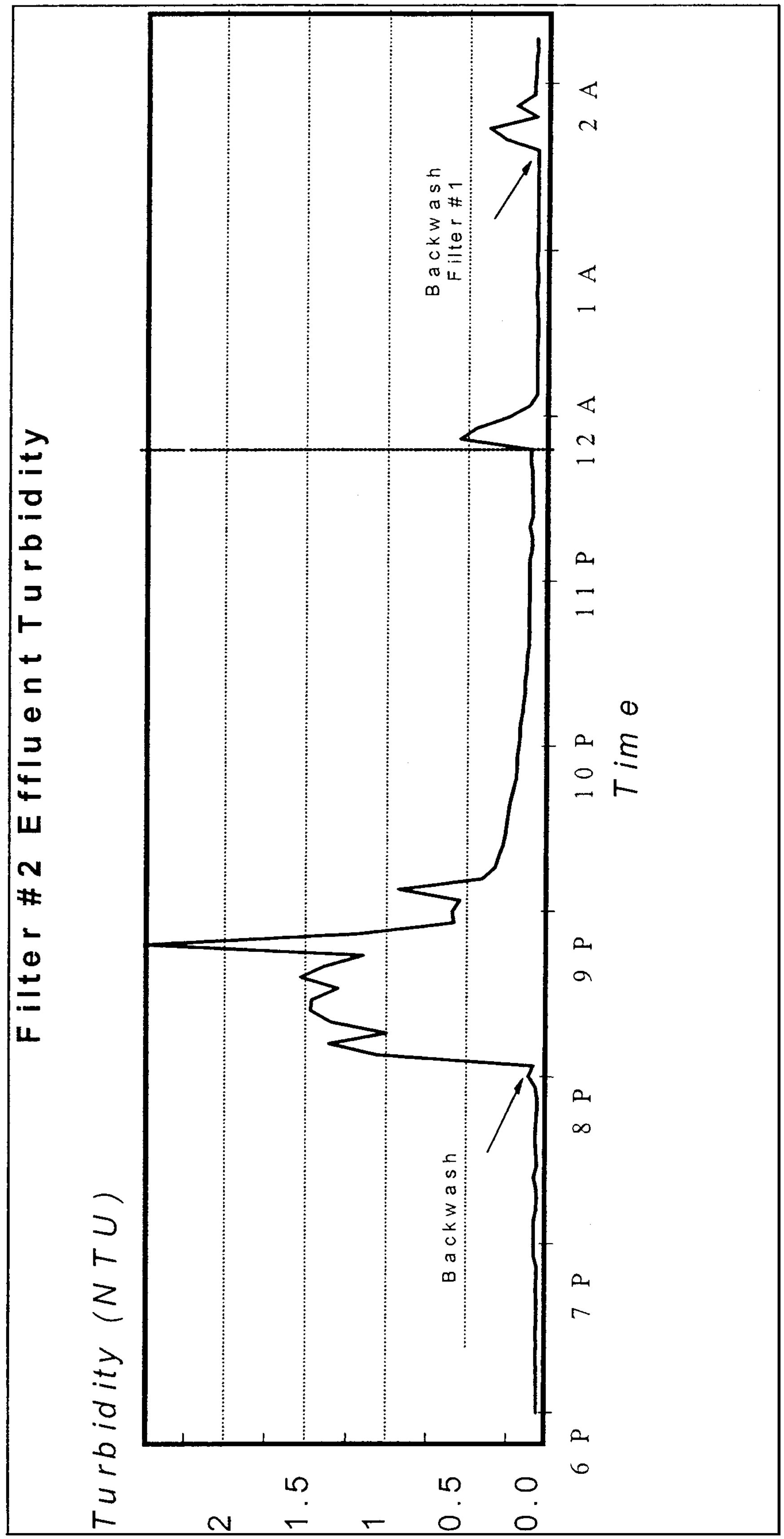
Figure IV.4. Example Filter Profile Depicting Turbidity Spikes



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Studies considered by both EPA and the M–DBP Advisory Committee noted that the greatest potential for a peak in turbidity (and thus, pathogen breakthrough) is near the beginning of the filter run after filter backwash or start up of operation (Amirtharajah, 1988; Bucklin, et al. 1988; Cleasby, 1990; and Hall and Croll, 1996). This phenomenon is depicted in Figure IV.4. Turbidity spikes also may occur for a variety of other reasons. These include:

- Outages or maintenance activities at processes within the treatment train;
- Coagulant feed pump or equipment failure;
- Filters being run at significantly higher loading rates than approved;
- Disruption in filter media;
- Excessive or insufficient coagulant dosage; and
- Hydraulic surges due to pump changes or other filters being brought on/off-line.

A recent study was completed which evaluated particle removal by filtration throughout the country. While the emphasis of this study was particle counting and removal, fifty-two of the 100 plants surveyed were also surveyed for turbidity with on-line turbidimeters. While all of the plants were able to meet 0.5 NTU 95 percent of the time, it was noted that there was a significant occurrence of spikes during the filter runs. These were determined to be a major source of raising the 95th percentile value for most of the filter runs. (McTigue *et al.* 1998)

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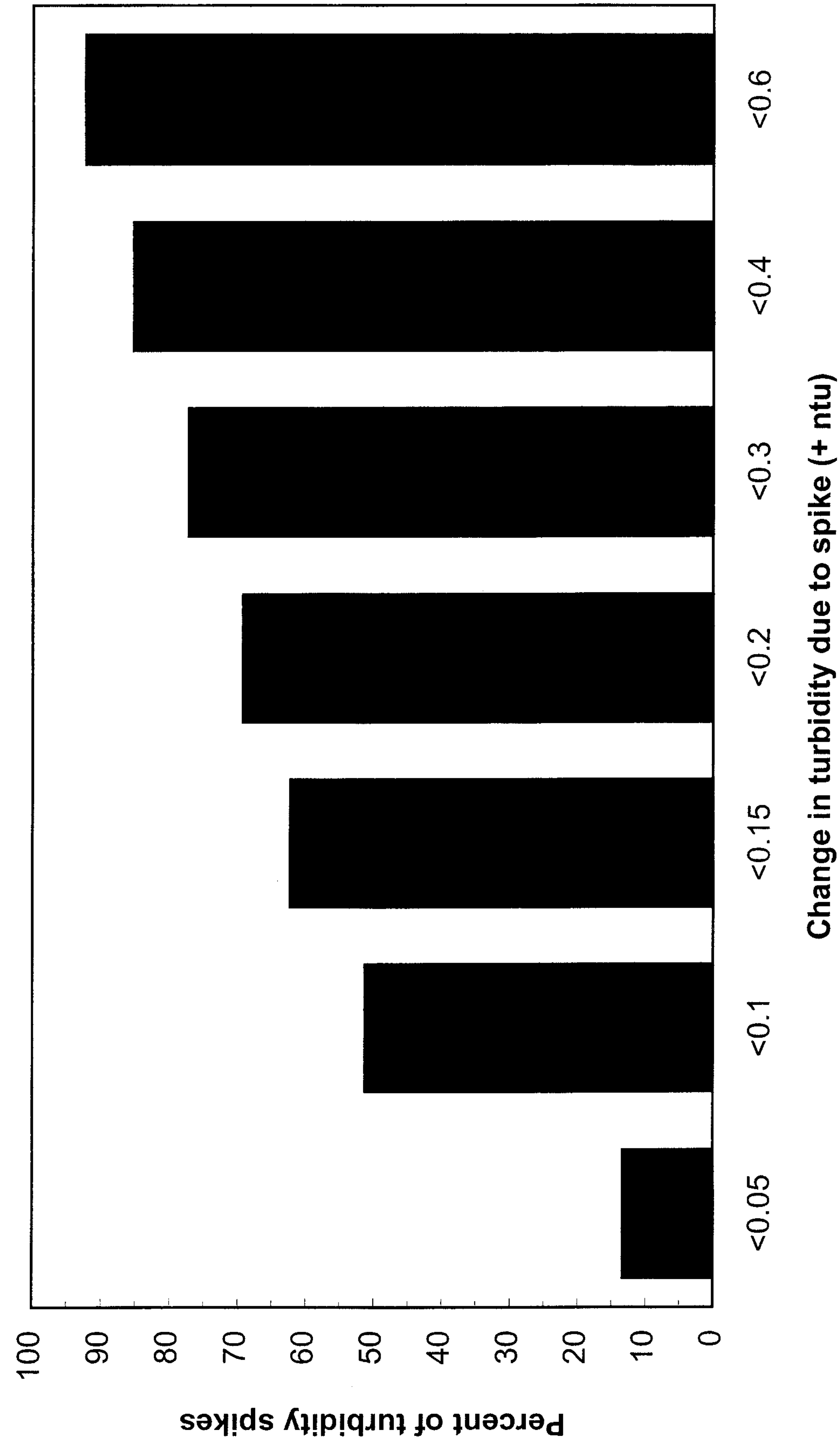


Figure IV.5a Results of Filter Turbidity Spike Analysis - Ripening Spikes by Change in Turbidity (McTigue 1998, Photorevised EPA 2000)

Figure IV.5b Results of Filter Turbidity Spike Analysis - Ripening Spikes by Duration (McTigue 1998, Photorevised EPA 2000)

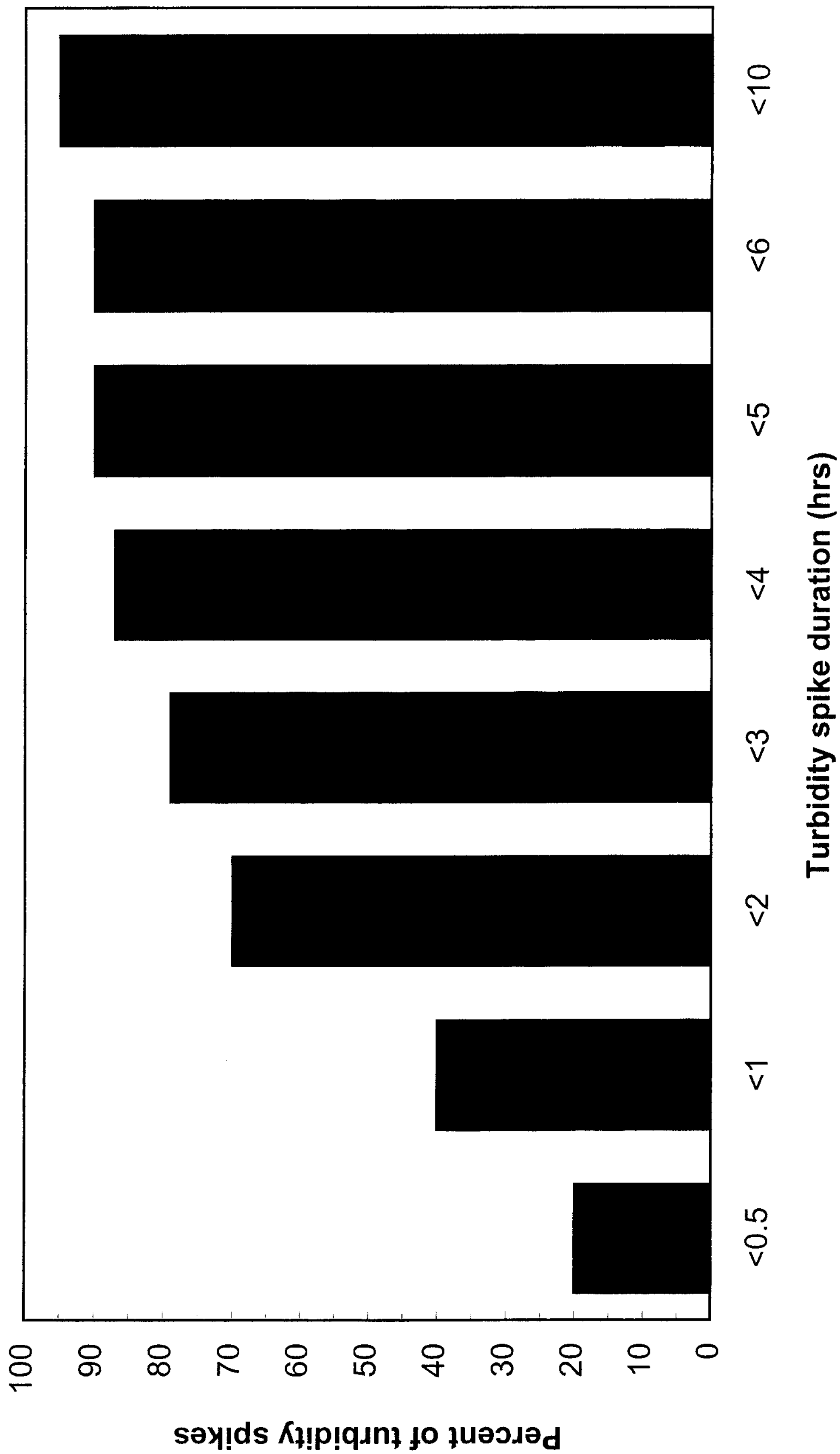


Figure IV.5c Results of Filter Turbidity Spike Analysis - Middle of Run Spikes by Change in Turbidity (McTigue 1998, Photorevised EPA 2000)

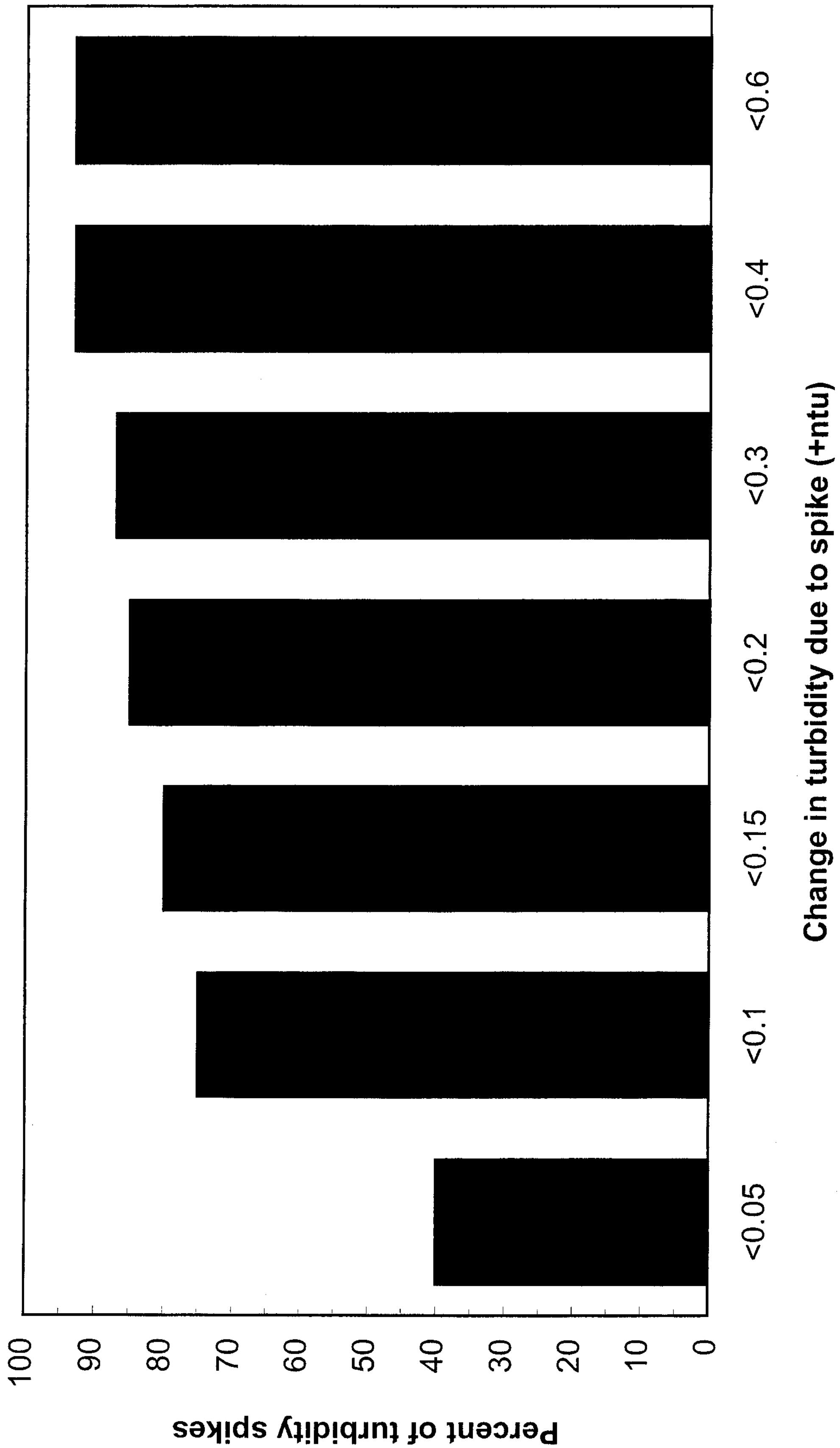


Figure IV.5d Results of Filter Turbidity Spike Analysis - Middle of Run Spikes by Change in Turbidity (McTigue 1998, Photorevised EPA 2000)

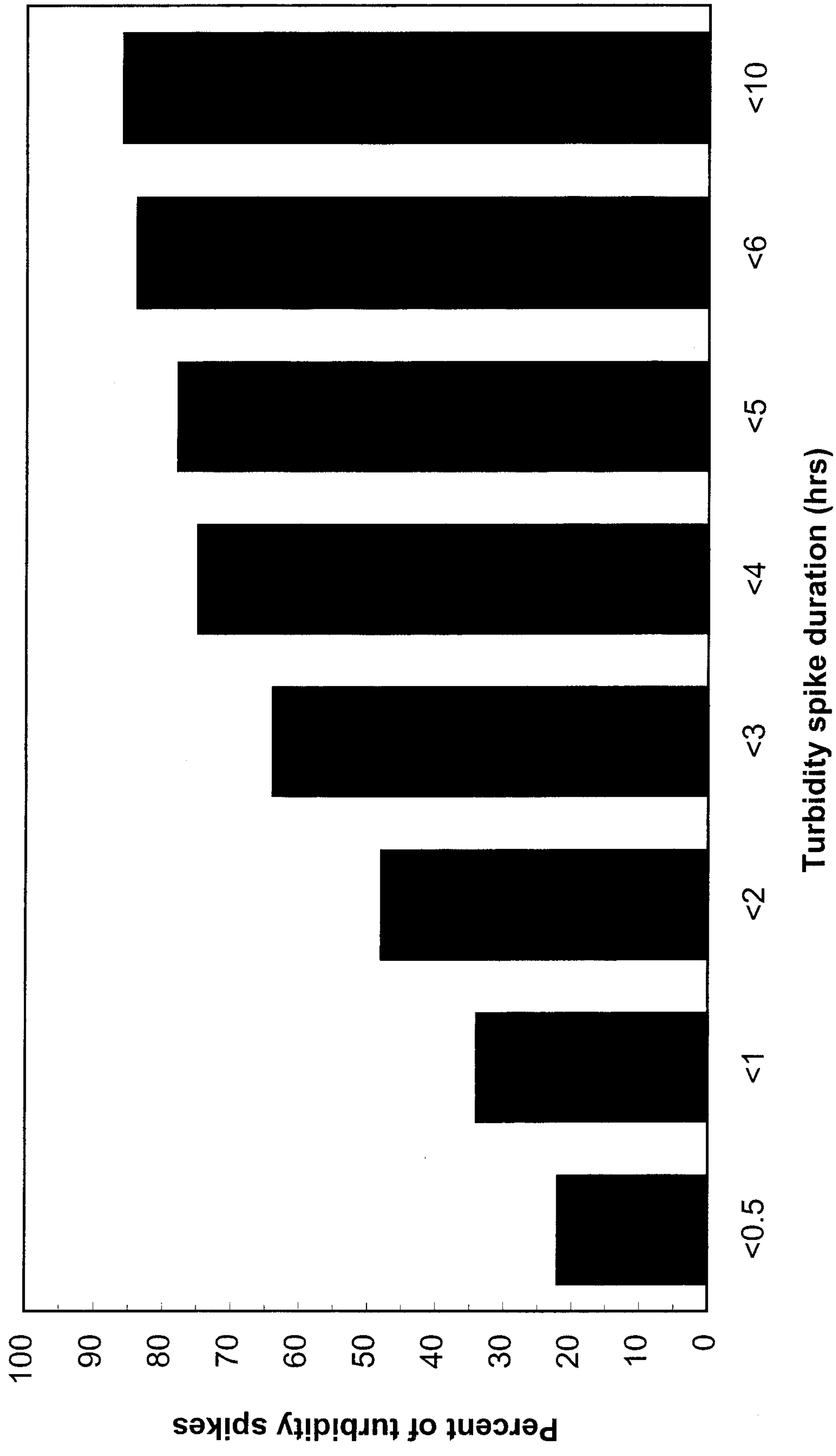


Figure IV.5e Results of Filter Turbidity Spike Analysis - End of Run Spikes by Change in Turbidity (McTigue 1998, Photorevised EPA 2000)

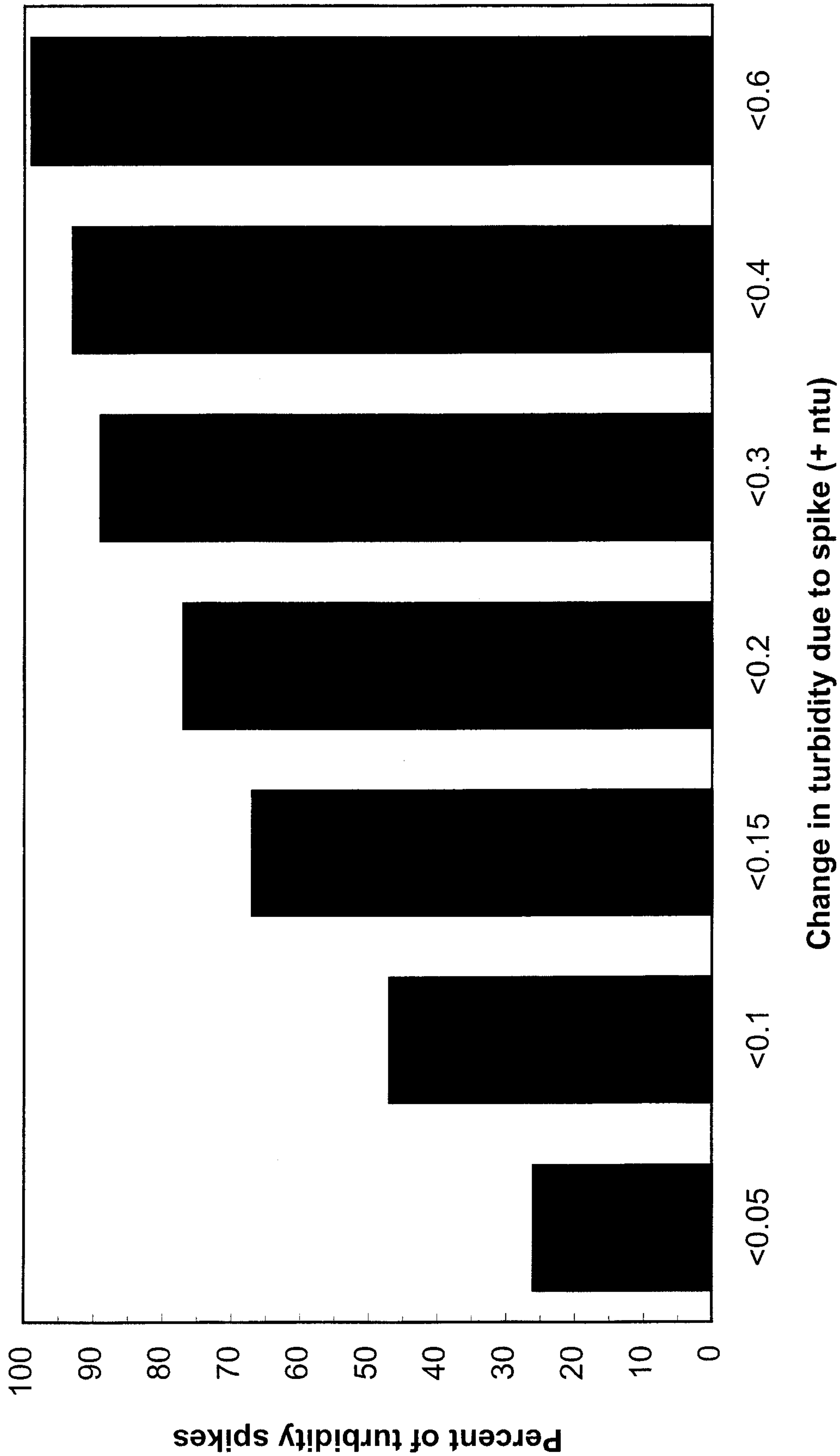
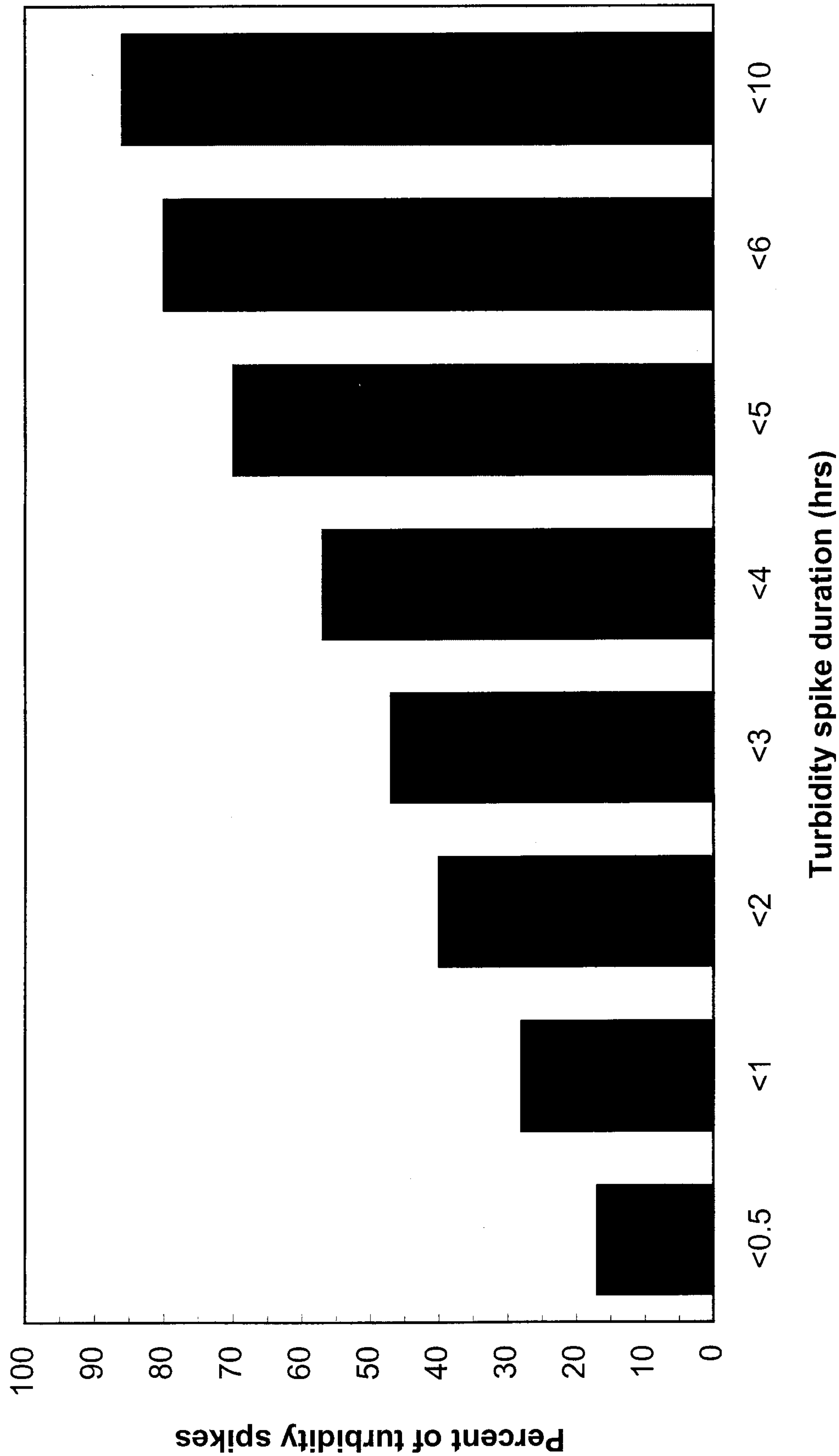


Figure IV.5f Results of Filter Turbidity Spike Analysis - End of Run Spikes by Duration
(McTigue 1998, Photorevised EPA 2000)



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Masking of Filter Performance

Combined Filter Effluent monitoring can mask poor performance of individual filters which may allow passage of particulates (including *Cryptosporidium* oocysts). One poorly performing filter, can be effectively ''masked'' by other well operated filters because water from each of the filters is combined before an effluent turbidity measurement is taken. The following example illustrates this phenomenon.

The fictitious City of ''Smithville'' (depicted in Figure IV.6) operates a conventional filtration plant with four rapid granular filters as shown below. Filter number 1 has significant problems because the depth and placement of the media are contributing to elevated turbidities. Filters 2, 3, and 4 do not have these problems and are operating properly.

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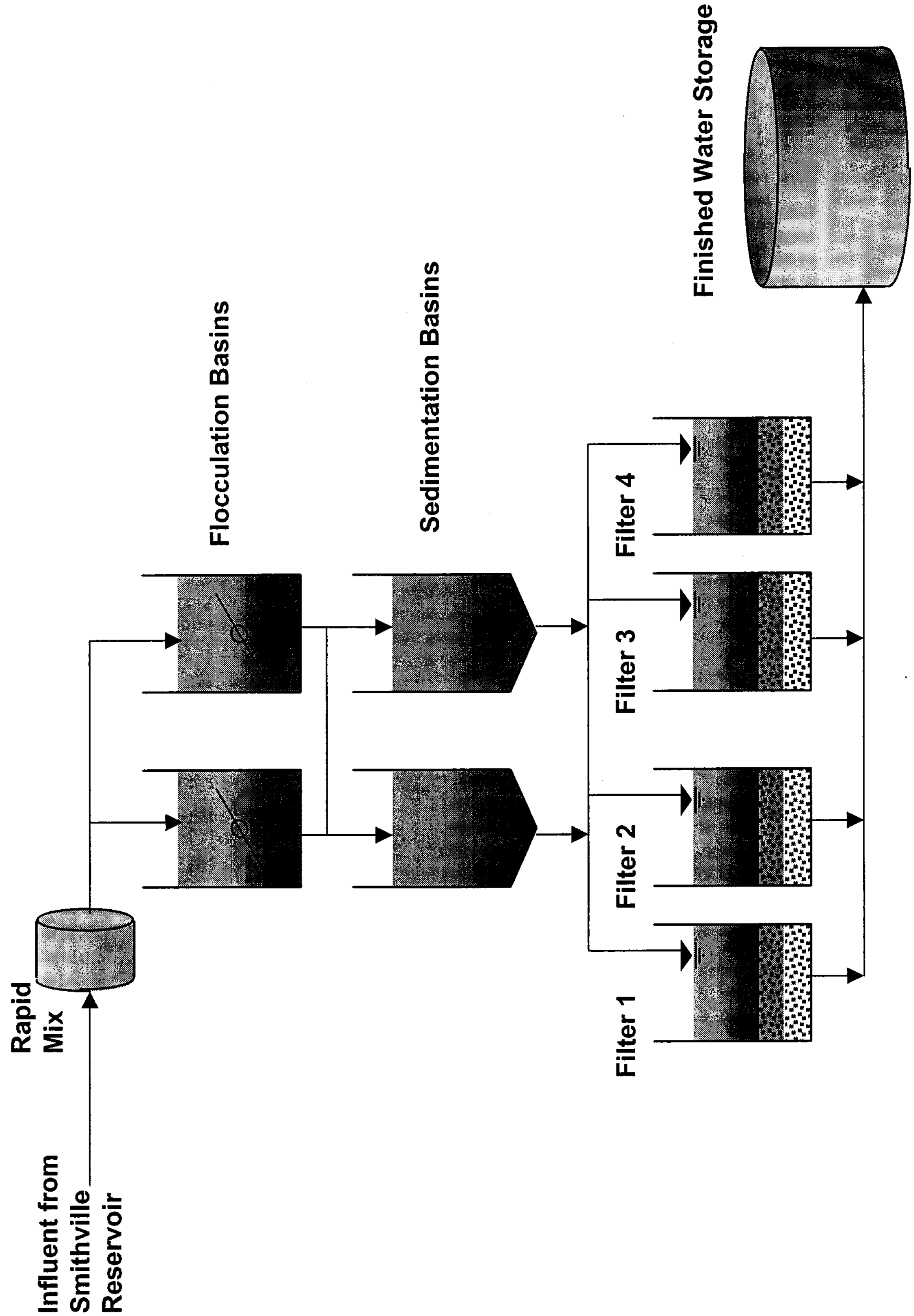
Figure IV.6 Schematic of Conventional Treatment Plant



Turbidity measurements taken at the clearwell indicate 0.3 NTU. Filter 4 produces water with a turbidity of 0.08 NTU, Filter 3 a turbidity of 0.2 NTU, Filter 2 a turbidity of 0.1 NTU, and Filter 1 a turbidity of 0.9 NTU. Each filter contributes an equal proportion of water, but each is operating at different turbidity levels which contributes to the combined filter effluent of 0.32 NTU. ([0.08+0.2+0.1+0.9]÷4 = 0.32 NTU)

As discussed previously in Section IV.2.a, the Agency believes that a system must meet 0.3 NTU 95 percent of the time an appropriate treatment technique requirement that assures an increased level of *Cryptosporidium* removal. While the fictitious system described above would barely meet the required CFE turbidity, it is entirely possible that they would not be achieving an overall 2 log removal of *Cryptosporidium* with one filter achieving considerably less than 2-log removal. This issue highlights the importance of understanding the performance of individual filters relative to overall plant performance.

iii. Proposed Requirements

Today's proposed rule establishes an individual filter turbidity requirement which applies to all surface water and GWUDI systems using filtration and which serve populations fewer than 10,000 and utilize direct or conventional filtration. In developing this requirement, the Agency evaluated several alternatives (A, B and C) in an attempt to reduce the burden faced by small systems while still providing: (1) A comparable level of public health protection as that afforded to systems serving 10,000 or more people and (2) an early-warning tool systems can use to detect and correct problems with filters.

Alternative A

The first alternative considered by the Agency was requiring direct and conventional filtration systems serving populations fewer than 10,000 to meet the same requirements as established for systems serving 10,000 or more people. This alternative would require that all conventional and direct filtration systems must conduct continuous monitoring of turbidity (one turbidity measurement every 15 minutes) for each individual filter. Systems must provide an exceptions report to the State as part of the existing combined filter effluent reporting process for any of the following circumstances:

(1) Any individual filter with a turbidity level greater than 1.0 NTU based on two consecutive measurements fifteen minutes apart;

(2) Any individual filter with a turbidity greater than 0.5 NTU at the end of the first four hours of filter operation based on two consecutive measurements fifteen minutes apart;

(3) Any individual filter with turbidity levels greater than 1.0 NTU based on two consecutive measurements fifteen minutes apart at any time in each of three consecutive months (the system must, in addition to filing an exceptions report, conduct a self-assessment of the filter); and

(4) Any individual filter with turbidity levels greater than 2.0 NTU based on two consecutive measurements fifteen minutes apart at any time in each of two consecutive months (the system must file an exceptions report and must arrange for a comprehensive performance evaluation (CPE) to be conducted by the State or a third party approved by the State).

Under the first two circumstances identified, a system must produce a filter profile if no obvious reason for the abnormal filter performance can be identified.

Alternative B

The second alternative considered by the Agency represents a slight modification from the individual filter monitoring requirements of large systems. The 0.5 NTU exceptions report trigger would be omitted in an effort to reduce the burden associated with daily data evaluation. Additionally, the filter profile requirement would be removed. Requirement language was slightly modified in an effort to simplify the requirement for small system operators. This alternative would still require that all conventional and direct filtration systems conduct *continuous* monitoring (one turbidity measurement every 15 minutes) for each individual filter, but includes the following three requirements:

(1) A system must provide an exceptions report to the State as part of the existing combined effluent reporting process if any individual filter turbidity measurement exceeds 1.0 NTU (unless the system can show that the next reading is less than 1.0 NTU);

(2) If a system is required to submit an exceptions report for the same filter in three consecutive months, the system must conduct a self-assessment of the filter.

(3) If a system is required to submit an exceptions report for the same filter in two consecutive months which contains an exceedance of 2.0 NTU by the same filter, the system must arrange for a CPE to be conducted by the State or a third party approved by the State.

Alternative C

The third alternative considered by the Agency would include new triggers for reporting and follow-up action in an effort to reduce the daily burden associated with data review. This alternative would still require that all conventional and direct filtration systems must conduct *continuous* monitoring (one turbidity measurement every 15 minutes) for each individual filter, but would include the following three requirements:

(1) A system must provide an exceptions report to the State as part of the existing combined effluent reporting process if filter samples exceed 0.5 NTU in at least 5 percent of the measurements taken each month and/or any individual filter measurement exceeds 2.0 NTU (unless the system can show that the following reading was < 2.0 NTU).

(2) If a system is required to submit an exceptions report for the same filter in three consecutive months the system must conduct a self-assessment of the filter.

(3) If a system is required to submit an exceptions report for the same filter in two consecutive months which contains an exceedance of 2.0 NTU by the same filter, the system must arrange for a CPE to be conducted by the State or a third party approved by the State.

For all three alternatives the requirements regarding self assessments and CPEs are the same. If a CPE is required, the system must arrange for the State or a third party approved by the State to conduct the CPE no later than 30 days following the exceedance. The CPE must be completed and submitted to the State no later than 90 days following the exceedance which triggered the CPE. If a self-assessment is required it must take place within 14 days of the exceedance and the system must report to the State that the self-assessment was conducted. The self assessment must consist of at least the following components:

- assessment of filter performance;
- development of a filter profile;
- identification and prioritization of factors limiting filter performance;
- assessment of the applicability of corrections; and
- preparation of a filter self assessment report.

In considering each of the above alternatives, the Agency attempted to reduce the burden faced by small systems. Each of the three alternatives was judged to provide levels of public health protection comparable to those in the IESWTR for large systems. Alternative A, because it contains the same requirements as IESWTR, was expected to afford the same level of public health protection. Alternative B, (which removes the four-hour 0.5 NTU trigger and the filter profile requirement) was expected to afford comparable health protection because the core components which provide the overwhelming majority of the public health protection (monitoring frequency, trigger which requires follow-up action, and the follow-up actions) are the same as the IESWTR. Alternative C was expected to provide comparable health protection because follow-up action is the same as under the IESWTR and a 0.5 NTU 95percent percentile trigger was expected to identify the same systems which the triggers established under the IESWTR would identify. All three were also considered useful diagnostic tools for small systems to evaluate the performance of filters and correct problems before follow-up action was necessary. The first alternative was viewed as significantly more challenging to implement and burdensome for smaller systems due to the amount of required daily data review. This evaluation was also echoed by small entity representatives during the Agency's SBREFA process as well as stakeholders at each of the public meetings held to discuss issues related to today's proposed rule. While Alternative C reduced burden associated with daily data review, it would institute a very different trigger for small systems than established by the IESWTR for large systems. This was viewed as problematic by several stakeholders who stressed the importance of maintaining similar requirements in order to limit transactional costs and additional State burden. Therefore, the Agency is proposing Alternative B as described above, which allows operators to expend less time to evaluate their turbidity data. Alternative B maintains a comparable level of public health protection as those afforded large systems, reduces much of the burden associated with daily data collection and review (removing the requirement to conduct a filter profile allows systems to review data once a week instead of daily if they so choose), yet still serves as a self-diagnostic tool for operators and provides the mechanism for State follow-up when significant performance problems exist.

iv. Request for Comments

The individual filter monitoring provisions represent a challenging opportunity to provide systems with a useful tool for assessing filters and correcting problems before State intervention is necessary or combined filter turbidity is affected and treatment technique violations occur. The Agency is actively seeking comment on this provision. Because of the complexity of this provision, specific requests for comment have been broken down into five distinct areas.

Comments on the Alternatives

EPA requests comment on today's proposed individual filter requirement and each of the alternatives as well as additional alternatives for this provision such as establishing a different frequency for individual filter monitoring (*e.g.,* 60 minute or 30 minute increments). The Agency also seeks comment or information on:

- Tools and or guidance which would be useful and necessary in order to educate operators on how to comply with individual filter provisions and perform any necessary calculations;
- Data correlating individual filter performance relative to combined filter effluent;
- Contributing factors to turbidity spikes associated with reduced filter performance;
- Practices which contribute to poor individual filter performance and filter spikes; and
- Any additional concerns with individual filter performance.

Modifications to the Alternatives

The Agency also seeks comment on a variety of proposed modifications to the individual filter monitoring alternatives discussed which could be incorporated in order to better address the concerns and realities of small surface water systems. These modifications include:

- Modification of the alternatives to include a provision which would require systems which do not staff the plant during all hours of operation, to utilize an alarm/phone system to alert off-site operators of significantly elevated turbidity levels and poor individual filter performance;
- A modification to allow conventional and direct filtration systems with either 2–3 or less filters to sample combined filter effluent continuously (every 15 minutes) in lieu of monitoring individual filter turbidity. This modification would reduce the data collection/analysis burden for the smallest systems while not compromising the level of public health protection;
- A modification to lengthen the period of time (120 days or a period of time established by the State but not to exceed 120 days) for completion of the CPE and/or a modification to lengthen the requirement that a CPE must be conducted no later than 60 or 90 days following the exceedance; and
- A modification to require systems to notify the State within 24 hours of triggering the CPE or IFA. This would inform States sooner so they can begin to work with systems to address performance of filters and conduct CPEs and IFAs as necessary.

Establishment of Subcategories

The Agency is also evaluating the need to establish subcategories in the final rule for individual filter monitoring/reporting. EPA is currently considering these three categories:

1. Systems serving populations of 3,300 or more persons;
2. Systems with more than 2 filters, but less than 3,300 persons; and
3. Systems with 2 or fewer filters serving populations fewer than 3,300 persons.

Individual filter monitoring requirements would also be based on these subcategories. Systems serving 3,300 or greater would be required to meet the same individual turbidity requirements as the IESWTR (Alternative A as described above). Systems serving fewer than 3,300 but using more than 2 filters would be required to meet a modified version of the IESWTR individual filter requirements (Alternative B as described above). Systems serving fewer than 3,300 and using 2 or fewer filters would continue to monitor and report only combined filter effluent turbidity at an increased frequency (once every 15 minutes, 30 minutes, or one hour).

Input and or comment on cut-offs for subcategories and how to apply subcategories to Alternatives is requested. The Agency would also like to take comment on additional strategies to tailor individual filter monitoring for the smallest systems while continuing to maintain an adequate level of public health protection. Such possible strategies include:

- Since small systems are often understaffed one approach would require those systems utilizing only two or fewer filters to utilize, maintain, and continually operate an alarm/phone system during all hours of operation, which alert off-site operators of significantly elevated turbidity levels and poor individual filter performance and/or automatically shuts the system down if turbidity levels exceed a specified performance level. This modification would be in addition to the proposed requirements.
- Establishing a more general modification which would require systems which do not staff the plant during all hours of operation to utilize

an alarm/phone system to alert off-site operators of significantly elevated turbidity levels and poor individual filter performance, and/or to automatically shut the system down if turbidity levels exceed a specified performance level.

• If systems with 2 or fewer filters is allowed to sample combined filter effluent in lieu of individual filter effluent with a frequency of a reading every hour and combined filter effluent turbidity exceeds 0.5 NTU, should the system be required to take grab samples of individual filter turbidity for all filters every 15 minutes until the results of those samples are lower than 0.5 NTU?

Reliability

Maintaining reliable performance at systems using filtration requires that the filters be examined at intervals to determine if problems are developing. This can mean that a filter must go off-line for replacement or upgrades of media, underdrains, backwash lines etc. In order to provide adequate public health protection at small systems, the lack of duplicate units can be a problem. EPA is considering requiring any system with only one filter to install an additional filter. The schedule would be set by the primacy agency, but the filter would have to be installed no later than 6 years after promulgation. EPA is requesting comment on this potential requirement.

Data Gathering Recordkeeping and Reporting

The Agency is evaluating data gathering/reporting requirements for systems. A system collecting data at a frequency of once every 15 minutes, (and operating) 24 hours a day, would record approximately 2800 data points for *each* filter throughout the course of the month. Although the smallest systems in operation today routinely operate on the average of 4 to 12 hours a day (resulting in 480 to 1400 data points per filter), these systems do not typically use sophisticated data recording systems such as SCADAs. The lack of modern equipment at small systems may result in difficulty with retrieving and analyzing data for reporting purposes. While the Agency intends to issue guidance targeted at aiding these systems with the data gathering requirements, EPA is also seeking feedback on a modification to the frequency of data gathering required under each of the aforementioned options. Specifically, the Agency would like to request comment on modifying the frequency for systems serving fewer than 3,300 to continuous monitoring on a 30 or 60 minute basis. EPA also requests comment on the availability and practicality of data systems that would allow small systems, State inspectors, and technical assistance providers to use individual filter turbidity data to improve performance, perform filter analysis, conduct individual filter self assessments, etc. The Agency is interested in *specific* practical combinations of data recorders, charts, hand written recordings from turbidimeters, that would accomplish this.

Failure of Continuous Turbidity Monitoring

Under today's proposed rule, the Agency requires that if there is a failure in the continuous turbidity monitoring equipment, the system must conduct grab sampling every four hours in lieu of continuous monitoring until the turbidimeter is back on-line. A system has five working days to resume continuous monitoring before a violation is incurred. EPA would like to solicit comment on modifying this component to require systems to take grab samples at an increased frequency, specifically every 30 minutes, 1 hour, or 2 hours.

B. Disinfection Benchmarking Requirements

Small systems will be required to comply with the Stage 1 Disinfection Byproduct Rule (Stage 1 DBPR) in the first calendar quarter of 2004. The Stage 1 DBPR set Maximum Contaminant Levels (MCLs) for Total Trihalomethanes (chloroform, bromodichloromethane, chlorodibromomethane, and bromoform), and five Haloacetic Acids (i.e., the sum of the concentrations of mono-, di-, and trichloroacetic acids and mono- and dibromoacetic acids.) The LT1FBR follows the principles set forth in earlier FACA negotiations, i.e., that existing microbial protection must not be significantly reduced or undercut as a result of systems taking the necessary steps to comply with the MCL's for TTHM and HAA5 set forth in Stage 1 DBPR. The disinfection benchmarking requirements are designed to ensure that risk from one contaminant is not increased while risk from another contaminant is decreased.

The Stage 1 DBPR was promulgated because disinfectants such as chlorine can react with natural organic and inorganic matter in source water and distribution systems to form disinfection byproducts (DBPs). Results from toxicology studies have shown several DBPs (e.g., bromodichloromethane, bromoform, chloroform, dichloroacetic acid, and bromate) to potentially cause cancer in laboratory animals. Other DBPs (e.g., certain haloacetic acids) have been shown to cause adverse reproductive or developmental effects in laboratory animals. Concern about these health effects may cause public water utilities to consider altering their disinfection practices to minimize health risks to consumers.

A fundamental principle, therefore, of the 1992–1993 regulatory negotiation reflected in the 1994 proposal for the IESWTR was that new standards for control of DBPs must not result in significant increases in microbial risk. This principle was also one of the underlying premises of the 1997 M–DBP Advisory Committee's deliberations, i.e., that existing microbial protection must not be significantly reduced or undercut as a result of systems taking the necessary steps to comply with the MCL's for TTHM and HAA5 set forth in Stage 1 DBPR. The Advisory Committee reached agreement on the use of microbial profiling and benchmarking as a process by which a PWS and the State, working together, could assure that there would be no significant reduction in microbial protection as the result of modifying disinfection practices in order to comply with Stage 1 DBPR.

The process established under the IESWTR has three components: (1) Applicability Monitoring; (2) Disinfection Profiling; and (3) Disinfection Benchmarking. These components have the following three goals respectively: (1) determine which systems have annual average TTHM and HAA5 levels close enough to the MCL (e.g., 80 percent of the MCL) that they may need to consider altering their disinfection practices to comply with Stage 1 DBPR; (2) those systems that have TTHM and HAA5 levels of at least 80 percent of the MCLs must develop a baseline of current microbial inactivation over the period of 1 year; and (3) determine the benchmark, or the month with the lowest average level of microbial inactivation, which becomes the critical period for that year.

The aforementioned components were applied to systems serving 10,000 or more people in the IESWTR and were carried out sequentially. In response to concerns about early implementation (any requirement which would require action prior to 2 years after the promulgation date of the rule), the Agency is considering modifying the IESWTR approach for small systems, as described in the following section. Additionally, the specific provisions have been modified to take into account specific needs of small systems. EPA's goal in developing these requirements is to recognize the specific needs of small system and States, while providing small systems with a useful means of ensuring that existing microbial protection must not be significantly reduced or undercut as a result of systems taking the necessary steps to comply with the MCL's for TTHM and HAA5 set forth in Stage 1 DBPR.

The description of the disinfection benchmarking components of today's proposed rule will be broken into the three segments: (1) Applicability Monitoring; (2) Disinfection Profiling; and (3) Disinfection Benchmarking. Each section will provide an overview and purpose, data, a description of the proposed requirements, and request for comment.

1. Applicability Monitoring

a. Overview and Purpose

The purpose of the TTHM and HAA5 applicability monitoring is to serve as an indicator for systems that are likely to consider making changes to their disinfection practices in order to comply with the Stage 1 DBPR. TTHM samples which equal or exceed 0.064 mg/L and/or HAA5 samples equal or exceed 0.048 mg/L (80 percent of their respective MCLs) represent DBP levels of concern. Systems with TTHM or HAA5 levels exceeding 80 percent of the respective MCLs may consider changing their disinfection practice in order to comply with the Stage 1 DBPR.

b. Data

In 1987, EPA established monitoring requirements for 51 unregulated synthetic organic chemicals. Subsequently, an additional 113 unregulated contaminants were added to the monitoring requirements. Information on TTHMs has become available from the first round of monitoring conducted by systems serving fewer than 10,000 people.

Preliminary analysis of the data from the Unregulated Contaminant Information System (URCIS, Data) suggest that roughly 12 percent of systems serving fewer than 10,000 would exceed 64 μ/L or 80 percent of the MCL for TTHM (Table IV.7). This number is presented only as an indicator, as it represents samples taken at the entrance to distribution systems. In general, TTHMs and HAA5s tend to increase with time as water travels through the distribution system. The Stage 1 Disinfection Byproducts Rule estimated 20 percent of systems serving fewer than 10,000 would exceed 80 percent of the MCLs for either TTHMs or HAA5s or both. EPA is working to improve the knowledge of TTHM and HAA5 formation kinetics in the distribution systems for systems serving fewer than 10,000 people. EPA is currently developing a model to predict the formation of TTHM and HAA5 in the distribution system based on operational measurements. This model is not yet available. In order to develop a better estimate of the percent of small systems that would be triggered into the profiling requirements (i.e., develop a profile of microbial inactivation over a period of 1 year) EPA is considering the following method:

- Use URCIS data to show how many systems serving 10,000 or more people have TTHM levels at or above 0.064 mg/L;
- Compare those values to the data received from the Information Collection Rule for TTHM average values taken at representative points in the distribution system;
- Determine the mathematical factor by which the two values differ; and
- Apply that factor to the URCIS data for systems serving fewer than 10,000 people to estimate the percent of those systems that would have TTHM values at or above 0.064mg/L as an average of values taken at representative points in the distribution system.

TABLE IV.7.—TTHM LEVELS AT SMALL SURFACE SYSTEMS

[Data from Unregulated Contaminant Database, 1987–92 [1]]

System size (population served)	Total number of systems	Number of systems w/ ave. TTHM ≥ 64 μg/L (80 % of MCL)	Maximum level of ave. TTHM (μg/L)
<500	74	0 (0%)	56
501–1,000	44	6 (13.6%)	222
1,001–3,300	114	12 (10.5%)	172
3,301–10,000	116	25 (21.6%)	279
Total	348	43 (12.4%)	279

[1] In Unregulated Contaminant Database (1987–1992), there are ten States (*i.e.*, CA, DE, IN, MD, MI, MO, NC, NY, PR, WV). However, only eight of them can be identified with the data of both population and TTHM for systems serving fewer than 10,000 people (See next page).

The Agency requests comment on this approach to estimating TTHM levels in the distribution system based on TTHM levels at the entry point to the distribution system. The Agency also requests comment on the relationship of HAA5 formation relative to TTHM formation in the distribution system. Specifically, is there data to support the hypothesis that HAA5s do not peak at the same point in the distribution system as TTHMs?

The Agency also received two full years of TTHM data for seventy-four systems in the State of Missouri (Missouri, 1998). This data consisted of quarterly TTHM data, which was converted into an annual average. The data (presented in Table IV.8) demonstrates a very different picture than that displayed by the URCIS data described above. In 1996, 88 percent of the systems exceeded 64 μg/L, while in 1997, 85 percent exceeded 64 μg/L. Figure IV.7 graphically displays this data set.

TABLE IV.8.—TTHM LEVELS AT SMALL SURFACE SYSTEMS IN THE STATE OF MISSOURI

[State of Missouri, 1996, 1997]

Year	Total number of systems	Number of systems w/ ave. TTHM ≥ 64 µg/L (80 percent of MCL)	Maximum Level of Ave. TTHM (µg/L)
1996	74	65 (88%)	276
1997	75	64 (85%)	251
All years	149	129 (87%)	276

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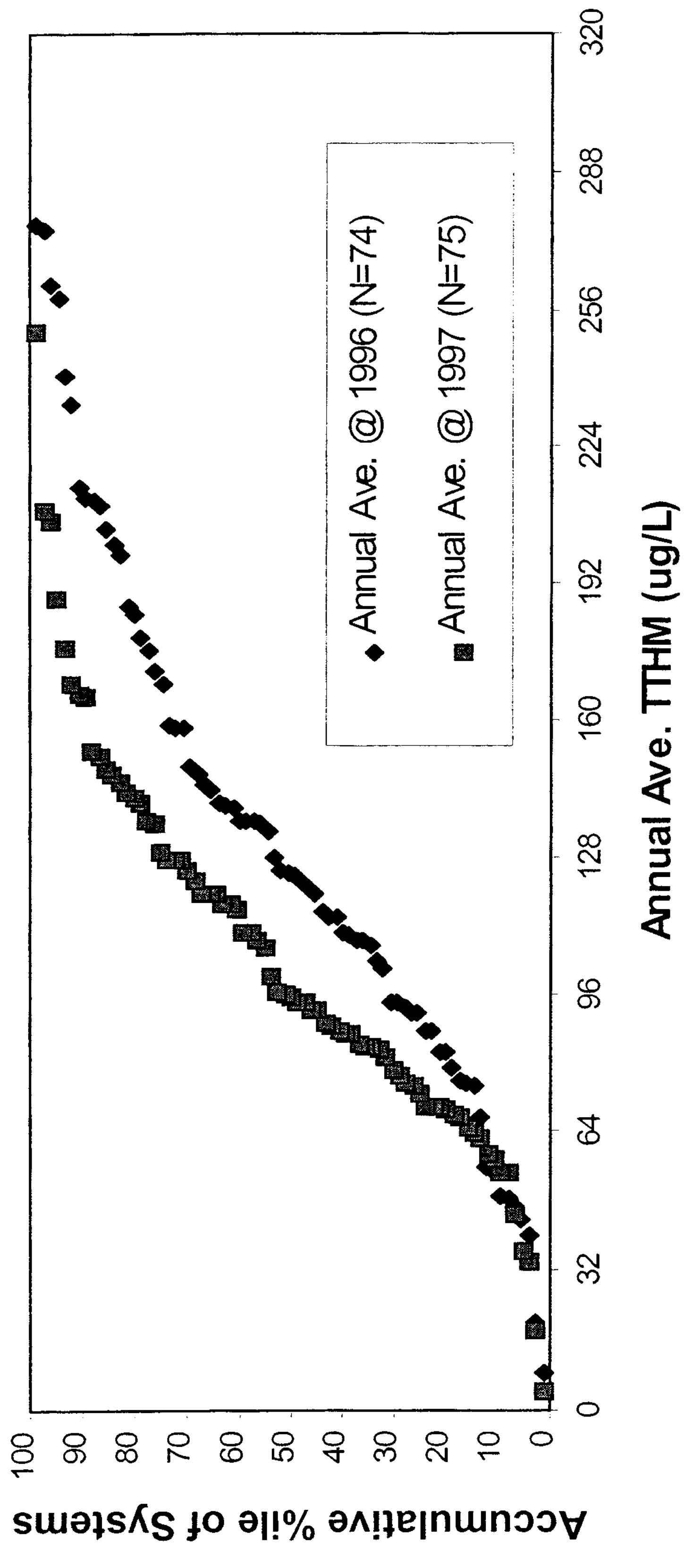

Figure IV.7 Distribution of Annual Ave. TTHM for Small SW Systems (<10,000) in Missouri

There are several potential reasons for the differences between the data shown in Tables IV.7 and IV.8. Data in Table IV.7 contains zero values which may be indicative of no sample being taken rather than a sample with a value of zero. Additionally, data shown in IV.8 was collected within the distribution system, while data in Table IV.7 was taken at the entry point to the distribution system. The data collection method used in collecting the data shown in Table IV.8 is similar to the methodology required under the Stage 1 DBPR.

c. Proposed Requirements

EPA considered four alternatives for systems to use TTHM and HAA5 data to determine which systems whether they would be required to develop a disinfection profile. In today's proposed rule, EPA is proposing Alternative 4.

Alternative 1

The IESWTR required that systems monitor for TTHMs at four points in the distribution system each quarter. At least one of those samples must be taken at a point which represents the maximum residence time of the water in the system. The remaining three must be taken at representative locations in the distribution system, taking into account number of persons served, different sources of water and different treatment methods employed. The results of all analyses per quarter are averaged and reported to the State.

EPA considered applying this alternative to systems serving fewer than 10,000 people and requested input from small system operators and other interested parties, including the public. Based on the feedback EPA received, two other alternatives were developed for consideration (listed as Alternatives 2 and 3).

Alternative 2

EPA considered requiring systems serving fewer than 10,000 people to monitor for TTHM and HAA5 at the point of maximum residence time according to the following schedule:

- No less than once per quarter per treatment plant operated for systems serving populations between 500 and 10,000 persons; and no less than once per year per treatment plant during the month of warmest water temperature for systems serving populations less than 500. If systems wish to take additional samples, however, they would be permitted to do so.
- Systems may consult with States and elect not to perform TTHM and HAA5 monitoring and proceed directly with the development of a disinfection profile.

This alternative provides an applicability monitoring frequency identical to the DBP monitoring frequency under the Stage 1 DBPR that systems will have to comply with in 2004. In addition, it allows systems the flexibility to skip TTHM and HAA5 monitoring completely, pending State approval, and begin profiling immediately.

Alternative 3

EPA considered requiring all systems serving fewer than 10,000 people to monitor once per year per system during the month of warmest water temperature of 2002 and at the point of maximum residence time.

During the SBREFA process and during stakeholder meetings, EPA received some positive comments regarding Alternative 3 as the least burdensome approach. Other stakeholders, however, pointed out that Alternative 3 does not allow systems to measure seasonal variation as is done in Alternative 2 for systems serving populations between 500 and 10,000. Several stakeholders agreed that despite the costs, the information obtained from applicability monitoring will be useful. EPA agrees that it is valuable to systems to monitor and understand the seasonal variation in TTHM and HAA5 values, however, EPA has determined that requiring a full year of monitoring may place an excessive burden on both States and systems. In order to complete a full year of monitoring and another full year of disinfection data gathering, systems would have to start TTHM and HAA5 monitoring January of 2002.

Under SDWA, States have two years to develop their own regulations as part of their primacy requirements, EPA recognized that requiring Applicability Monitoring during this period would pose a burden on States. In response to these concerns, the Agency developed a new alternative, described in the following paragraph.

Alternative 4

Applicability Monitoring is optional and not a requirement under today's proposed rule. If a system has TTHM and HAA5 data taken during the month of warmest water temperature (from 1998–2002) and taken at the point of maximum residence time, they may submit this data to the State prior to [DATE 2 YEARS AFTER PUBLICATION OF FINAL RULE]. If the data shows TTHM and HAA5 levels less than 80 percent of the MCLs, the system does not have to develop a disinfection profile. If the data shows TTHM and HAA5 levels at or above 80 percent of the MCLs, the system would be required to develop a disinfection profile in 2003 as described later in section IV.B.2. If the system does not have, or does not gather TTHM and HAA5 data during the month of warmest water temperature and at the point of maximum residence time in the distribution system as described, then the system would automatically be required to develop a disinfection profile starting January 1 of 2003. This option still provides systems with the necessary tools for assessing potential changes to their disinfection practice, (i.e. the generation of the profile), while not forcing States to pass their primacy regulations, contact all small systems within their jurisdiction, and set up TTHM and HAA5 monitoring all within the first year after promulgation of this rule. Systems will still be able to ensure public health protection by having the disinfection profile when monitoring under Stage 1 DBPR takes effect. It should be noted that EPA estimates the cost for applicability monitoring (as described in Alternative 4) and disinfection profiling (as described in Alternative 3 in Section IV.B.2.c of this preamble) are roughly equivalent. EPA anticipates that systems with known low levels of TOC may opt to conduct the applicability monitoring while the remaining systems will develop a disinfection profile.

d. Request for Comment

EPA requests comment on the proposed requirement, other alternatives listed, or other alternatives that have not yet been raised for consideration. The Agency also requests comment on approaches for determining the percent of systems that would be affected by this requirement. Specifically:

- With respect to Alternative 4, the Agency requests comment on approaches for determining the percent of systems that might demonstrate TTHM and HAA5 levels less than 80 percent of their respective MCLs and would therefore not develop a disinfection profile.
- The Agency requests additional information (similar to the State of Missouri data discussed previously) on the current levels of TTHM and HAA5s in the distribution systems of systems serving fewer than 10,000 people.
- The Agency requests comment on developing a TTHM and HAA5 monitoring scheme during the winter months as opposed to the current monitoring scheme based on the highest TTHM/HAA5 formation potential during the month of warmest water temperature. If a relationship can be established, and shown to be consistent through geographical variations, EPA would consider modifying an alternative so that applicability monitoring would occur during the 1st quarter of 2003.
- The Agency requests comment on modifying Alternative 3, to require systems to begin monitor for TTHMs and HAA5s during the warmest water temperature month of 2003. The results of this monitoring would be used to

determine whether a system would need to develop a disinfection profile during 2004. This option is closer in structure and timing to the IESWTR and has been included for comment. It should be noted, however, that postponing the disinfection profile until 2004 would prevent systems from having inactivation data prior to their compliance date with the Stage 1 DBPR, possibly compromising simultaneous compliance.

2. Disinfection Profiling

a. Overview and Purpose

The disinfection profile is a graphical representation showing how disinfection varies at a given plant over time. The profile gives the plant operator an idea of how seasonal changes in water quality and water demand can have a direct effect on the level of disinfection the plant is achieving.

The strategy of disinfection profiling and benchmarking stemmed from data provided to the EPA and M–DBP Advisory Committee by PWSs and reviewed by stakeholders. The microbial inactivation data (expressed as logs of *Giardia lamblia* inactivation) used by the M–DBP Advisory Committee demonstrated high variability. Inactivation varied by several log on a day-to-day basis at any particular treatment plant and by as much as tens of logs over a year due to changes in water temperature, flow rate (and, consequently, contact time), seasonal changes in residual disinfectant, pH, and disinfectant demand and, consequently, disinfectant residual. There were also differences between years at individual plants. To address these variations, M–DBP stakeholders developed the procedure of profiling inactivation levels at an individual plant over a period of at least one year, and then establishing a benchmark of minimum inactivation as a way to characterize disinfection practice. This approach makes it possible for a plant that may need to change its disinfection practice in order to meet DBP MCLs to determine the impact the change would have on its current level of disinfection or inactivation and, thereby, to assure that there is no significant increase in microbial risk. In order to develop the profile, a system must measure four parameters (EPA is assuming most small systems use chlorine as their disinfection agent, and these requirements are based on this assumption):

(1) Disinfectant residual concentration (C, in mg/L) before or at the first customer and just prior to each additional point of disinfectant addition;

(2) Contact time (T, in minutes) during peak flow conditions;

(3) Water temperature (°C); and

(4) pH.

Systems convert this operational data to a number representing log inactivation values for *Giardia* by using tables provided by EPA. Systems graph this information over time to develop a profile of their microbial inactivation. EPA will prepare guidance specifically developed for small systems to assist in the development of the disinfection profile. Several spreadsheets and simple programs are currently available to aid in calculating microbial inactivation and the Agency intends to make such spreadsheets available in guidance.

b. Data

Figure IV.8a depicts a hypothetical disinfection profile showing seasonal variation in microbial inactivation.

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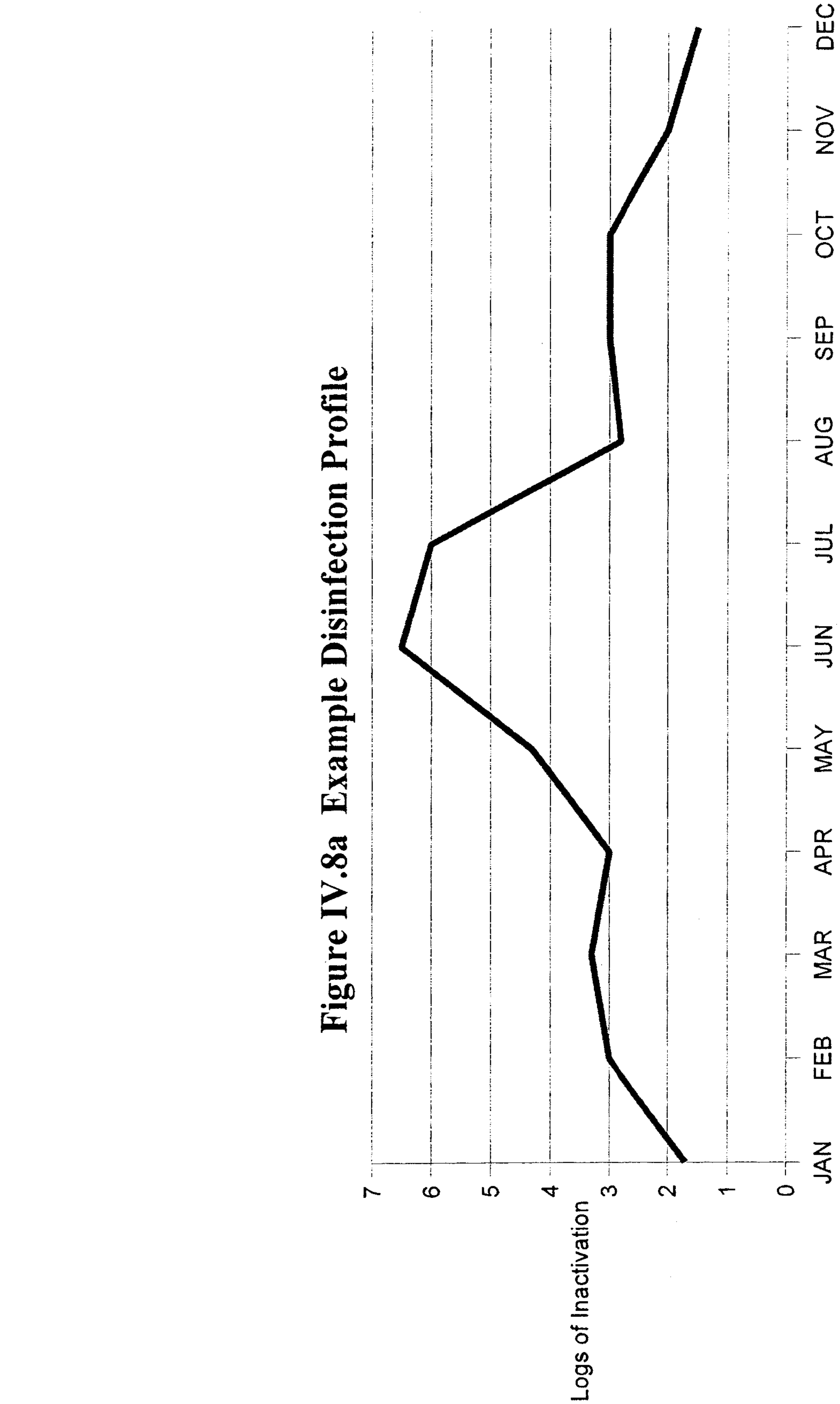

Figure IV.8a Example Disinfection Profile

c. Proposed Requirements

EPA considered four alternatives for requiring systems to develop the disinfection profile.

Alternative 1

The IESWTR requires systems serving 10,000 or more persons to measure the four parameters described above and develop a profile of microbial inactivation on a daily basis. EPA considered extending this requirement to systems serving fewer than 10,000 persons and requested input from small system operators and other interested stakeholders including the public. EPA received feedback that this requirement would place too heavy of a burden on the small system operator for at least two reasons:

- Small system operators are not present at the plant every day; and
- Small systems often have only one operator at a plant who is responsible for all aspects of maintenance, monitoring and operation.

Alternative 2

EPA also considered not requiring the disinfection profile at all. After consideration of the feedback of small system operators and other interested stakeholders, however, EPA believes that there is a strong benefit in the plant operator knowing the level of microbial inactivation, and that the principles developed during the regulation negotiation and Federal Advisory Committee prior to promulgation of the IESWTR could be applied to small systems for the purpose of public health protection. Recognizing the potential burdens the profiling procedures placed on small systems, EPA considered two additional alternatives.

Alternative 3

EPA considered requiring *all* systems serving fewer than 10,000 persons, to develop a disinfection profile based on *weekly* measurements for one year during or prior to 2003. A system with TTHM and HAA5 levels less than 80 percent of the MCLs (based on either required or optional monitoring as described in section IV.B.1) would not be required to conduct disinfection profiling. EPA believes this alternative would save the operator time (in comparison to Alternative 1), and still provide information on seasonal variation over the period of one year.

Alternative 4

Finally, EPA considered a monitoring requirement only during a one month critical monitoring period to be determined by the State. In general, colder temperatures reduce disinfection efficiency. For systems in warmer climates, or climates that do not change very much during the course of the year, the State would identify other critical periods or conditions. This alternative reduces the number of times the operator has to calculate the microbial inactivation.

EPA considered all of the above alternatives, and in today's proposed rule, EPA is proposing Alternative 3. First, this alternative does not require systems to begin monitoring before States have two years to develop their regulations as part of primacy requirements. Given early implementation concerns, the timing of this alternative appears to be the most appropriate in balancing early implementation issues with the need for systems to prepare for implementation of the Stage 1 DBPR and ensuring adequate and effective microbial protection. Second, it allows systems and States which have been proactive in conducting applicability monitoring to reduce costs for those systems which can demonstrate low TTHM and HAA5 levels. Third, this alternative allows systems and States the opportunity to understand seasonal variability in microbial disinfection. Finally, this alternative takes into account the flexibility needed by the smallest systems while maintaining comparable levels of public health protection with the larger systems.

Request for Comments

EPA requests comment on this proposed requirement as well as Alternatives 1,2, and 4. The Agency also requests comment on a possible modification to Alternatives 1, 3 and 4. Under this modification, systems serving populations fewer than 500 would have the opportunity to apply to the State to perform the weekly inactivation calculation (although data weekly data collection would still be required). If the system decided to make a change in disinfection practice, then the State would assist the system with the development of the disinfection profile.

The Agency also requests comment on a modification to Alternative 3 which would require systems to develop a disinfection profile in 2004 only if Applicability Monitoring conducted in 2003 indicated TTHM and HAA5 levels of 80 percent or greater of the MCL. This modification would be coupled with the applicability monitoring modification discussed in the previous section.

3. Disinfection Benchmarking

a. Overview and Purpose

The DBPR requires systems to meet lower MCLs for a number of disinfection byproducts. In order to meet these requirements, many systems will require changes to their current disinfection practices. In order to ensure that current microbial inactivation does not fall below those levels required for adequate *Giardia* and virus inactivation as required by the SWTR, a disinfection benchmark is necessary. A disinfection benchmark represents the lowest average monthly *Giardia* inactivation level achieved by a system. Using this benchmark States and systems can begin to understand the current inactivation achieved at the system, and estimate how changes to disinfection practices will affect inactivation.

b. Data

Based on the hypothetical disinfection profile depicted in Figure IV.8a, the benchmark, or critical period, is the lowest level of inactivation achieved by the system over the course of the year. Figure IV.8b shows that this benchmark (denoted by the dotted line) takes place in December for the hypothetical system.

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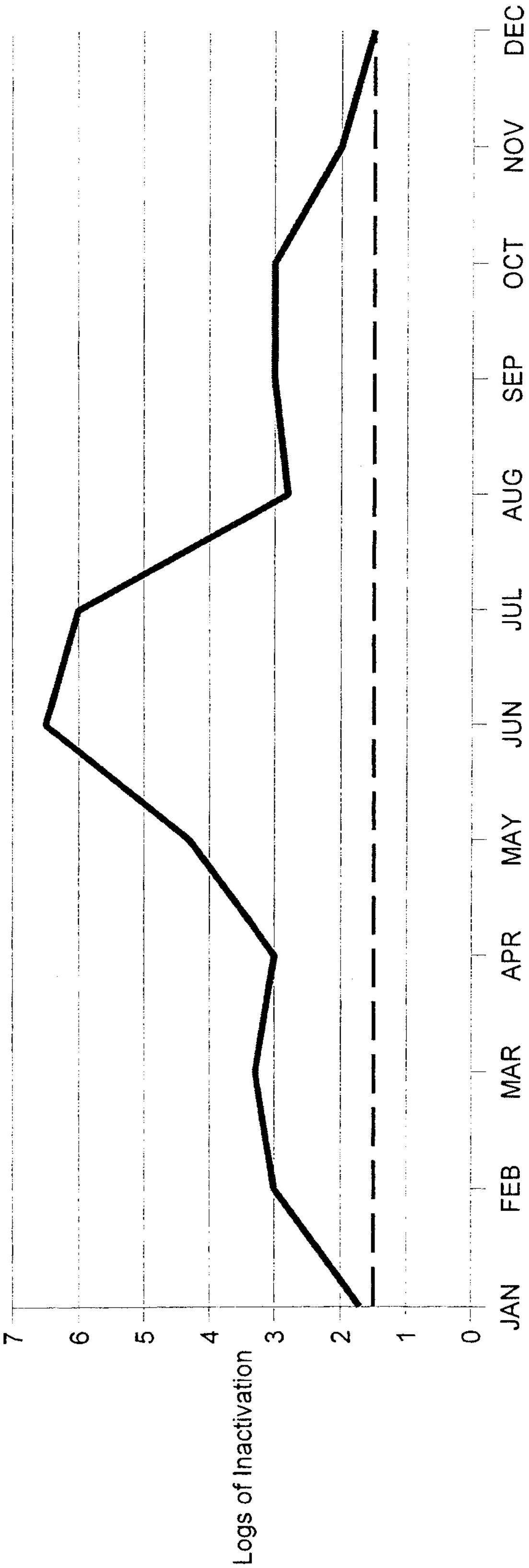
Figure IV.8b Example Disinfection Profile with Benchmark



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